In the Matter of

CERTAIN ELECTRONIC CHROMATOGRAM ANALYZERS

Investigation No. 337-TA-251

USITC PUBLICATION 2012

AUGUST 1987

United States International Trade Commission / Washington, DC 20436

UNITED STATES INTERNATIONAL TRADE COMMISSION

COMMISSIONERS

Susan Liebeler, Chairman
Anne E. Brunsdale, Vice Chairman
Alfred E. Eckes
Seeley G. Lodwick
David B. Rohr

Address all communications to
Kenneth R. Mason, Secretary to the Commission
United States International Trade Commission
Washington, DC 20436

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC 20436

In the Matter of

CERTAIN ELECTRONIC CHROMATOGRAM ANALYZERS

Investigation No. 337-TA-251

NOTICE OF TERMINATION OF INVESTIGATION ON THE BASIS OF NO VIOLATION OF SECTION 337 OF THE TARIFF ACT OF 1930

AGENCY: U.S. International Trade Commission.

ACTION: Determination of no violation of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, in the above-captioned investigation.

SUMMARY: The Commission has determined to affirm, with modifications, the initial determination (ID) of the presiding administrative law judge (ALJ) in the above-captioned investigation. The investigation is therefore terminated on the basis that there is no violation of section 337.

FOR FURTHER INFORMATION CONTACT: Jean H. Jackson, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202-523-1693.

SUPPLEMENTARY INFORMATION: On June 4, 1986, Bioscan Inc. filed a complaint under section 337. On July 9, 1986, the Commission instituted this investigation to determine whether there is a violation of section 337 in the unlawful importation and sale of certain electronic chromatogram analyzers into the United States by reason of alleged infringement of claims 5, 8, and/or 9 of U.S. Letters Patent 4,019,057, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States. The Commission named as respondents Isomess, Isotopenmessgerate GmbH of the Federal Republic of Germany; Aloka Company of Japan; IN/US Service Corporation of Fairfield, New Jersey; and Radiomatic Instruments & Chemical Co., Inc. of Tampa, Florida.

On April 9, 1987, the ALJ issued an ID finding no violation of section 337. On June 2, 1987, the Commission determined to review the issues of patent validity (obviousness), patent infringement, and domestic industry. (52 Fed. Reg. 22009). The parties submitted briefs on remedy, the public interest, and bonding. No other submissions were received.

The authority for the Commission's disposition of this matter is contained in section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) and in section 210.56 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.56).

Copies of the Commission's Action and Order, the nonconfidential version of the ID, 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, 701 E Street NW., Washington, DC 20436, telephone 202-523-0161. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission TDD terminal on 202-724-0002.

By order of the Commission.

Kenneth R. Mason
Secretary

Issued: July 9, 1987

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC 20436

In the Matter of CERTAIN ELECTRONIC CHROMATOGRAM ANALYZERS	)	Investigation No. 337-TA-251

COMMISSION ACTION AND ORDER

Background

On June 4, 1986, a complaint was filed with the Commission under section 337 on behalf of complainant Bioscan Inc. of Washington, D.C., naming as respondents Isomess, Isotopenmessgerate GmbH of the Federal Republic of Germany; Aloka Company of Japan; IN/US Service Corporation of Fairfield, New Jersey; and Radiomatic Instruments & Chemical Co., Inc. of Tampa, Florida. On July 9, 1986, the Commission instituted the above-captioned investigation to determine whether there is a violation of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) in the unlawful importation and sale of certain electronic chromatogram analyzers by reason of alleged infringement of claims 5, 8, and/or 9 of U.S. Letters Patent 4,019,057 (the '057 patent), the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States. (51 Fed. Reg. 24945-6).

On April 9, 1987, the presiding administrative law judge (ALJ) issued an initial determination (ID) finding no violation of section 337 in the investigation. On June 2, 1987, the Commission determined to review the issues of patent validity (obviousness), patent infringement, and domestic industry. (52 Fed. Reg. 22009). The parties submitted briefs on the issues of remedy, the public interest, and bonding. No other submissions were received.

Action

Having considered the ALJ's ID, the briefs of the parties, and the record in this investigation, the Commission has determined to affirm, with modifications, the ALJ's findings concerning patent validity (obviousness), patent infringement, and domestic industry. Accordingly, the Commission has determined to terminate the investigation on the basis that there is no violation of section 337.

For those issues addressed in the ALJ's ID that the Commission determined not to review, the ID has become the determination of the Commission.

Order

Accordingly, it is hereby ORDERED THAT—

1. Those portions of the ALJ's ID concerning the issues of patent validity (obviousness), patent infringement, and the domestic industry are affirmed with modifications;

2. Investigation No. 337-TA-251 is terminated on the basis that there is no violation of section 337; and

3. The Secretary shall serve copies of this Action and Order and the Opinion (to be issued later) in connection therewith upon each party of record in this investigation and upon the Department of Health and Human Services, the Department of Justice, the Federal Trade Commission, and the U.S. Customs Service, and publish notice thereof in the Federal Register.

By order of the Commission.

Kenneth R. Mason
Secretary

Issued: July 9, 1987

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of CERTAIN ELECTRONIC CHROMATOGRAM ANALYZERS	)	Investigation No. 337-TA-251

COMMISSION OPINION 1/

INTRODUCTION

This investigation is based on a complaint alleging unfair practices in the importation and sale of certain electronic chromatogram analyzers, the alleged effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States. The unfair practice alleged was direct infringement of claims 5, 8, and/or 9 of U.S. Letters Patent 4,019,057 (the '057 patent). Complainant Bioscan is the exclusive licensee of the '057 patent. The respondents are IN/US Service Corp.; Isomess, a division of Isotopenmessgerate GmbH; Radiomatic Instruments and Chemical Co., Inc.; and Aloka, Inc.

On April 9, 1987, the presiding administrative law judge (ALJ) issued an initial determination (ID) finding no violation of section 337 of the Tariff

1/ The following abbreviations are used in this Opinion: ALJ = Administrative Law Judge, CX = Complainant's Exhibit, CPX = Complainant's Physical Exhibit, FF = Finding of Fact Made in ID, IA = Commission Investigative Attorney, ID = Initial Determination, RX = Respondent's Exhibit, TR = Transcript of the Evidentiary Hearing.

Act of 1930. 2/ Complainant and the Commission investigative attorneys (IAs) filed petitions for review. 3/ On June 2, 1987, the Commission determined to review the issues of patent validity (obviousness), patent infringement, and domestic industry. 52 Fed. Reg. 22009 (June 10, 1987). The portions of the ID that were not reviewed became the Commission's determination pursuant to 19 C.F.R. § 210.53 (h). For reasons set out below, the Commission concurs in the ALJ's conclusion that there has been no violation of section 337.

SUMMARY OF THE ID

The ALJ found that claim 9 of the '057 patent was invalid because it was not enabled under 35 U.S.C. § 112, first paragraph. The ALJ determined that claims 5 and 8 were valid, but only if interpreted to include a limitation requiring pressurization of the detector chamber of the chromatogram analyzer—a limitation that is not set forth in the '057 claims. The ALJ found that if claims 5 and 8 were not so construed, they would be invalid as obvious in view of the prior art.

2/ 19 U.S.C. § 1337. For a discussion of the procedural background prior to the issuance of the initial determination see the ID at 3-3.

3/ Complainants petitioned for review of the issues of patent validity (obviousness and enablement), patent infringement, and domestic industry. The IAs petitioned for review of the issues of patent validity (obviousness only), patent infringement, and domestic industry. Respondents did not file a petition for review, but indicated in their response to the petitions that they supported the position taken by the IAs on the issues of obviousness and infringement. Respondents' Response to Complainant's and the IAs' Petitions for Review at 2-3.

The ALJ determined that neither respondents' nor complainant's chromatogram analyzers have detector chambers capable of being pressurized. Accordingly, the ALJ found that claims 5 and 8 were not infringed by the products imported by respondents and that complainant's products were not made in accordance with the '057 patent. Because the ALJ determined that the complaint's analyzer was not made in accordance with the '057 patent, he found that no domestic industry existed in this investigation. The ALJ determined, however, that if complainant's activities were found to constitute a domestic industry, the effect and tendency of the importation and sale of respondents' products would be to substantially injure the relevant domestic industry.

DISCUSSION

I. The Product [4/]

The products at issue are electronic imaging chromatogram analyzers. These devices are used in the analysis of radioactively-labeled samples prepared in connection with biomedical research. Research samples are labeled with radioactive isotopes which emit low energy beta particles (free electrons) that can be detected by the analyzers at issue. The detector chambers of these analyzers are charged with ionizable gas mixtures. Molecules of this gas mixture lose electrons (i.e., are ionized) as they are struck by particles emitted from the radioactively-labeled samples. Thus, the

---

4/ See ID at 5-6 for a more comprehensive description of the product at issue.

number of free electrons produced by the radioactively-labeled samples is multiplied many times over in the detector chamber by the electrons formed from the ionizable gas. The detector chamber contains a positively charged wire, called the anode, which attracts the negatively charged electrons released from the ionizable gas. The analyzer contains electronics capable of determining from the impact of the electrons on the anode wire both the spatial distribution and the amount of radioactive label in the samples. The term "imaging" refers to the ability of the analyzer to scan an entire chromatogram sample, typically 200 millimeters (mm) (about 8 inches) long, at one time. Mechanical scanners which predate imaging analyzers can measure only small portions of the chromatogram sample at a time and must be moved along the chromatogram sample mechanically.

II. The '057 Patent

The '057 patent, entitled "Device for Determining the Spatial Distribution of Radioactivity within an Object," issued April 19, 1977, and is assigned to the Institut Pasteur. The patent expires on April 19, 1994. Complainant Bioscan is the exclusive U.S. licensee of the '057 patent. During 1983 and 1984, the '057 patent was the subject of reexamination proceedings at the U.S. Patent and Trademark Office (PTO). [5/] At the conclusion of the

---

5/ The reexamination proceedings were requested by Berthold, a West German company that had been named as a respondent in an earlier ITC section 337 investigation which involved the same patent and the same complainant, Certain Electronic Chromatogram Analyzers, Inv. No. 337-TA-142. As part of the settlement agreement which formed the basis for terminating Inv. No. 337-TA-142, Berthold agreed to take a sublicense from Bioscan if the patentability of the '057 claims was confirmed by the PTO on reexamination.

reexamination proceedings, the patentability of all the claims of the '057 patent was confirmed by the PTO.

III. Presumption of Validity

The patent statute places the burden of proving facts establishing invalidity on the person asserting invalidity. The facts establishing invalidity must themselves be established by clear and convincing evidence. 6/ In this investigation, respondents introduced into evidence several prior art references that were not before the PTO in either the original or the reexamination proceedings concerning the '057 patent. The discovery of prior art that was not before the PTO can reduce or eliminate the amount of deference due to the PTO. 7/ However, regardless of whether the prior art has been before the PTO, each fact based on the prior art which forms the foundation of an ultimate conclusion of obviousness must be established by clear and convincing evidence. 8/

IV. Obviousness

A. Introduction.

35 U.S.C. § 103 provides, in pertinent part, as follows:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102

6/ Jones v. Hardy, 727 F.2d 1524, 1528, 220 USPQ 1021, 1024 (Fed. Cir. 1984).

7/ American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360, 220 U.S.P.Q. 763, 770 (Fed. Cir. 1984).

8/ Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F 2d 281, 292, 227 USPQ 657, 663 (Fed. Cir. 1985).

> of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. . . .

The Supreme Court set forth the following framework for analysis under 35 U.S.C. 103 in Graham v. John Deere Co., 383 U.S. 1 (1966):

> Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. . . . Such secondary considerations as commercial success, long felt but unresolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. 9/

B. Scope and Content of the Prior Art

The '057 patent concerns a method and apparatus for determining the spatial distribution of low energy radioactivity within a sample quickly and with high resolution. 10/ The ALJ determined that the following four categories of prior art put into evidence by respondents were relevant to the '057 claims at issue. 11/ (1) Conventional (mechanical) proportional counters (analyzers) 12/ which teach the placement of radioactive samples,

---

9/ Graham v. John Deere Co., 383 U.S. at 17-18 (1966).

10/ '057 patent (CX-4), Abstract. Only apparatus claims are at issue in this investigation.

11/ ID at 13-20.

12/ The electronics contained in proportional counters produce a signal that is proportional to the energy contained in the particle striking the anode wire. Non-proportional counters, such as Geiger counters, cannot distinguish the energy levels of the particles striking the anode wire. See TR at 314-316, FF 81.

including those labeled with low energy emitters (e.g., tritium and carbon-14), inside a gas-tight detector chamber for analyzing. After insertion of the sample, these detectors are completely enclosed except for a means to introduce the ionizing gas. [13/] (2) Conventional proportional counters which teach the placement of radioactive samples labeled with low energy isotopes outside the detector chamber but in close proximity to an opening in one wall of the chamber. [14/] In this type of counter, the sample lies within the electric field generated by the anode wire and the detector chamber walls, and ionizing gas flows over the samples. (3) Position-sensing electronics used in combination with the above described conventional proportional counters for operation as position sensitive proportional counters, which are able to locate the position of the radioactivity in the sample. [15/] (4) Multi-wire proportional counters which indicate position sensing on a two- or three-dimensional basis. Much of the prior art relied upon by the ALJ was not before the PTO in either the original examination or in the reexamination of the '057 patent.

13/ FF 90-102.

14/ FF 103-117.

15/ The ALJ, in fact, mischaracterized this category of prior art. The category that the ALJ referred to as "category 3" actually covers only position sensitive electronics in combination with conventional proportional counters which teach placement of the radioactive samples inside a gas-tight detector chamber for analysis (category 1). Category 3 does not cover the combination of the position sensitive electronics with conventional proportional counters which teach the placement of samples outside, but in close proximity to the detector chamber (category 2). See e.g., RX-1, RX-16.

C. Differences Between the Prior Art and the Claimed Invention

Though it is proper to note the difference in a claimed invention from the prior art, the invention must be considered as a whole when performing an obviousness analysis. It is improper to consider the difference between the prior art and the claimed subject matter to be the invention. 16/ The ALJ found that the only difference between claim 5 of the '057 patent 17/ and the prior art that was nonobvious was the detection of low energy beta particle radiation (free electrons) in a chamber pressurized beyond atmospheric pressure. 18/ A pressurization limitation, however, is not set forth in claim 5. 19/ We do not agree with the ALJ's interpretation of claim 5 concerning the requirement of a pressurization limitation because that

---

16/ Jones v. Hardy, 727 F.2d 1524, 1528, 220 U.S.P.Q. 1021, 1024 (Fed. Cir. 1984).

17/ The nonobviousness of claim 5 is determinative of nonobviousness in this investigation because the additional features of dependent claims 8 and 9, the other claims at issue in this investigation, were well known in the prior art. ID at 23. The additional features concern collimation (focusing or channeling) of the radioactivity in order to produce a finer resolution of the signals impinging upon the anode wire. Moreover, where as here, the patentability of a dependent claim is not argued separately, the validity of the dependent claim stands or falls with the underlying independent claim. In re Sernaker, 702 F.2d 989, 991, 217 U.S.P.Q. 1, 3 (Fed. Cir. 1983).

18/ ID at 22-23.

19/ Although the '057 patent specification describes an embodiment of the invention which provides improved resolution by use of a pressurized detector chamber ('057 patent CX-4, Col. 4, lines 35-42), the specification in no way limits the invention to this embodiment.

interpretation is at odds with basic principles of claim interpretation and is contrary to the evidence of record in this investigation. 20/

Claims 5, 8, and 9 do not make any reference to pressure, pressurization, operation at beyond atmospheric pressure, or any other such phenomenon. Portions of the '057 patent cited by the ALJ in support of the proposition that pressurization is required by claim 5, do not support the ALJ's conclusion. Those portions of the patent concern only a single embodiment of the invention. 21/ In addition, we find nothing in the prosecution history of the '057 patent, either in the original examination or in the reexamination, suggesting that claim 5 should be construed as requiring pressurization. We note that neither complainant nor respondents contend that claim 5 should be interpreted to include a pressurization limitation. Moreover, claim 7, a dependent claim not at issue here, includes the limitation that the detector chamber be operated at "significantly higher than atmospheric pressure." Under the doctrine of claim differentiation, which was acknowledged in the ID, it is improper to read into an independent claim a limitation that is explicitly set forth in a dependent claim. 22/

20/ Moreover, the record shows that pressurization of detector chambers to improve resolution is old in the art, and thus such a limitation could not "save" otherwise invalid claims from a finding of invalidity. Prior art references which teach pressurization of detectors include RX-16, RX-12, and RX-25.

21/ CX-4, Col. 4, lines 37-40; Col. 6, lines 33-35; See also CX-4, Col. 9, lines 1-9.

22/ Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 770, 218 U.S.P.Q. 781, 788 (Fed. Cir. 1983). The ALJ attempted to distinguish "higher than atmospheric pressure" from "significantly higher that atmospheric pressure". However, the record, including the patent specification and the '057 patent's prosecution history, does not support such a distinction.

There are several differences between the prior art and the analyzer claimed in the '057 patent that were not acknowledged in the ID. The prior art analyzers were mechanical strip scanners with detector slits that had to be moved along the chromatogram sample, a sample which is typically 200 mm long and 10 mm wide. The slits in these analyzers were typically 1-2 mm in width and 50 mm in length. The anode wires in the prior art analyzers were positioned perpendicular to the sample being analyzed. 23/ In contrast, the imaging analyzer of the '057 patent exposes its detector to the entire length and breadth of a chromatogram sample at one time. 24/ Moreover, the anode wire in the imaging analyzer is positioned parallel to the chromatogram sample. 25/

The '057 patent claims require that the chromatogram sample be positioned as close as possible to the anode wire in order to improve resolution. This teaching is not found in any of the prior art references of record. The prior art references teach, instead, placing the sample as close as possible to the detector. 26/

D. Level of Skill in the Art

We adopt the ALJ's findings and conclusions concerning the level of ordinary skill in the art. According to the ALJ, a person of ordinary skill

---

23/ RX-17, RX-27, RX-32, RX-42.

24/ TR 138

25/ CX-4, Col. 6, lines 62-64; Col. 9, lines 48-49.

26/ See RX-17, RX-27, RX-32, RX-42.

in the relevant art would have some educational background in physics, possibly only at an undergraduate level. He or she would also have either experience or education in electrical technology. Finally, this person would be generally familiar with the various scientific journals dealing with the art of radiation detection devices. 27/

E. Combining of References

References used in combination to establish invalidity must show some teaching or suggestion within the references which supports using their teachings in combination. 28/ The ALJ found that it would have been obvious to combine various pieces of prior art from four different categories to arrive at the invention of the '057 patent (if the invention were not construed to include a teaching concerning pressurization of the detector chamber). In effect, the ALJ found it would be obvious to replace the electronics found in certain prior art detectors with the electronics found in other types of prior art devices to make the invention of the '057 patent. In finding claim 5 of the '057 patent to be invalid for obviousness in view of the prior art, the ALJ relied on references that teach the major components of the '057 invention and testimony by respondents' experts that it would have been obvious to combine those references. 29/

27/ See ID at 23-4.

28/ Ashland Oil, Inc. v. Delta Resins & Refractories, 776 F.2d 281, 293, 227 U.S.P.Q 657, 664 (Fed. Cir. 1985); W.L. Gore & Associates Inc., v. Garlock, Inc., 721 F.2d 1540, 1551, 220 U.S.P.Q. 303, 311 (Fed. Cir. 1983).

29/ ID 21, FF 164-174.

The references relied upon by the ALJ do not themselves suggest combining their teachings. We note that the references do suggest the use of a position detecting anode wires for detecting the low energy emitters which are commonly used in chromatography. 30/ We do not find, however, that the references contain a sufficient suggestion or teaching for combining the various pieces of prior art in such a way as to develop the invention of the '057 patent. Moreover, we note that one of respondents' expert witnesses testified only that it would be obvious to try a combination of the prior art to develop the invention of the '057 patent. 31/ An "obvious to try standard" is not permitted under 35 U.S.C. § 103. 32/

F. Objective Indicia of Nonobviousness

Objective indicia of nonobviousness ("secondary considerations") must always be considered when present as an integral part of any obviousness analysis. 33/ In order to be probative of nonobviousness, however, a sufficient nexus must be established between the merits of the claimed invention and the objective indicia of nonobviousness. 34/ Complainant introduced evidence concerning the commercial success, long felt need, failure

---

30/ RX-1, RX-39, RX-40.

31/ FF-160, CX-134 (Rothberg Deposition) at 78-79, 102; TR 420, 448, 456-59.

32/ Jones v Hardy, 727 F.2d 1524, 1530, 220 U.S.P.Q 1021, 1026 (Fed. Cir. 1984).

33/ Simmons Fastener Corp. v. Illinois Tool Works, Inc., 739 F.2d 1573, 1575-76, 222 U.S.P.Q. 744, 746-47 (Fed. Cir. 1984).

34/ Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1539, 218 U.S.P.Q. 871, 879 (Fed. Cir. 1983).

of others, and copying of its commercial chromatogram analyzer. As we discuss more fully below, complainant's analyzer is not made in accordance with the '057 patent. Thus, there is no nexus between complainant's evidence relating to objective indicia of nonobviousness and the '057 patent. For reasons chiefly, but not limited to the lack of a nexus, the ALJ found that complainant's evidence relating to the objective indicia of obviousness did not establish that claim 5 is nonobvious. 35/ While the ALJ may not have accurately characterized the proper role of objective indicia in performing his obviousness analysis, 36/ we agree with his findings concerning the evidence relating to the objective indicia of nonobviousness. 37/ We determine, therefore, that complainant's evidence relating to objective indicia of nonobviousness does not have a sufficient nexus to the invention claimed in the '057 patent, and thus there are no "secondary considerations" bearing on the legal issue of obviousness in this investigation. 38/

35/ ID 32.

36/ We note the ALJ's statement that while "[h]ardly determinative on their own, secondary considerations may be persuasive particularly when a claim is not clearly obvious." ID at 25.

37/ FF 206-230a. We note that the ID did not discuss either the evidence that mechanical strip scanners had been completely replaced by the imaging chromatogram analyzers of complainant and respondents or a letter written by one of the respondents which praised Bioscan's analyzers (CX-27). This evidence is not probative of nonobviousness because it relates to chromatogram analyzers that are not made in accordance with the '057 patent. Moreover, the letter in question was based in its entirety on information given by complainant to respondent at a time when the parties had a business relationship. Respondents' Response to Complainant's and IAs' Petitions for Review at 4.

38/ See In re Vamco Machine and Tool, Inc., 752 F.2d 1564, 1577 (Fed. Cir. 1985).

G. Conclusion as to Obviousness

We determine that the record does not adequately support a finding that it would have been obvious to a person of ordinary skill in the art to combine the various pieces of prior art of record to arrive at the invention claimed in claims 5 and 8 of the '057 patent. Therefore, we determine that claims 5 and 8 of the '057 patent are not invalid because of obviousness.

VI. Infringement

A. Introduction

Complainant bears the burden to establish infringement by a preponderance of the evidence. 39/ Infringement is determined by comparing the accused infringing product with the properly construed claims of the patent, rather than with a preferred embodiment of the patent found in the specification or a commercial embodiment of the patentee. 40/ Infringement analysis entails two inquiries: determination of the scope of the claims, a question of law; and the factual finding of whether properly construed claims encompass the accused structure. 41/ This analytical framework applies whether claims are asserted to be infringed literally or by application of the doctrine of equivalents. 42/

39/ Hughes Aircraft Co. v. U.S., 717 F.2d 1351, 1361, 219 U.S.P.Q. 473, 480 (Fed. Cir. 1983).

40/ SRI International v. Matsushita Electric Corp. of America, 775 F.2d 1107, 1121, 227 U.S.P.Q. 577, 586 (Fed. Cir. 1985).

41/ Texas Instruments Inc. v. U.S.I.T.C., 805 F.2d 1558, 1562, 231 U.S.P.Q. 833, 834 (Fed. Cir. 1986).

42/ Id.

We adopt the ALJ's finding that for purposes of the infringement analysis, the chromatogram analyzers of respondents and complainant are identical. 43/ The detector chambers of these analyzers have one open side. 44/ During operation, the detectors of these analyzers are placed over the chromatogram sample (open side down), leaving a gap of approximately 1 mm between the sample and the detector chamber. 45/ The gap between the detector and the sample is necessary to prevent the detector from being contaminated with the radioactivity from the samples. 46/ The devices of both complainant and respondents are gas flow analyzers. 47/ During operation of the analyzers, ionizable gas continuously flows out of the detector and over the sample, filling the gap between the detector and the sample. 48/ For reasons discussed below, we determine that neither respondents' nor complainant's analyzers fall within the scope of the '057 claims.

43/ FF 265.

44/ FF 280-282. See also CPX-2. The commercial devices of the parties (CPX-1, RPX-1, RPX-2) were withdrawn as exhibits. Although CPX-2 is an earlier model, it is the same type of device as the analyzers at issue. TR 378, 728.

45/ Id.

46/ TR 358.

47/ FF 273, TR 506.

48/ FF-280-282. We note that an earlier model built by Bioscan (CPX-3) that was not commercially successful had a gas tight detector chamber. FF 277.

B. Claim Interpretation

Claim 5 of the '057 patent contains the following limitations:

> 1. a completely enclosed chamber containing an ionizable gas;
>
> 2. at least a portion of one wall of the enclosed chamber is removable;
>
> 3. an elongated conductor extending longitudinally in and fixedly secured within the enclosed chamber;
>
> 4. a support attached inside the chamber to mount a sample in close proximity and substantially parallel to the anode wire;
>
> 5. means for determining the location of radioactive particles along the length of the anode wire;
>
> 6. means for counting the number of radioactive particles at each one of a plurality of locations; and
>
> 7. a display device connected to the output of the counting means.

Claims are interpreted by analyzing the language of the claim, the patent documents, including the prosecution history ("file wrapper"), and expert testimony. 49/ Claims are construed as they would be by those of ordinary skill in the art. 50/

The parties dispute the interpretation of the claim language "completely enclosed chamber", "a removable portion of the chamber wall ", and a "support attached inside the detector chamber to mount a sample." Complainant argues

---

49/ Autogiro Company of America v. United States, 384 F.2d 391,155 U.S.P.Q. 697 (Ct. Cl. 1967).

50/ Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1571, 219 U.S.P.Q. 1137, 1142 (Fed. Cir. 1983).

that when in use the detector positioned over the sample constitutes a completely enclosed chamber, and that the removeable wall and support for mounting a sample can be combined into one structure. Complainant's expert (who is also the president of complainant Bioscan) testified that the term "completely enclosed chamber" can be interpreted to cover the structure that is formed when the detector chamber is placed over the sample holder. He also testified that the support inside the detector chamber and the removeable wall could be combined into one structure. 51/

Respondents argue that a gas flow analyzer placed over a sample with a 1 mm gap between the open side of the detector chamber and the sample cannot be an enclosed chamber. One of respondents experts testified that the term "enclosed chamber" means a chamber from which gas cannot escape. This expert noted that the patent drawings in the '057 patent specification show that the openings of the detector chamber are sealed with gaskets. 52/ Respondents' other expert testified that the French counterpart application of the '057 patent, from which the '057 patent claims priority, calls for a "hermetically sealed" detector chamber. 53/ This expert testified that his understanding of "completely enclosed chamber" was a closed box, in essence a sealed box. 54/ Respondents' expert also testified that a sample holder lying

---

51/ See Shulman testimony TR 182-186, 363.

52/ Rothberg testimony TR 422-3.

53/ Polic testimony TR 500.

54/ TR 499.

under a detector would not be a "support inside the detector chamber, but rather a support external to the chamber. 55/ The patent drawings show a box whose sides are fastened together with screws and sealed with gaskets. We also note that while a portion of the detector wall is removeable, it is secured to the detector chamber with screws. 56/

There is no indication in the patent specification or prosecution history to indicate that anything other than the plain meaning of the language "completely enclosed chamber", "removeable portion of the wall", or "support attached inside the detector chamber" was intended. We note that complainant's expert could do no more than assert that "a completely enclosed chamber" can be interpreted to cover the combination of a detector chamber and a sample holder. He pointed to nothing in the patent documents to support his interpretation. Based on the patent documents and expert testimony, we interpret the term "completely enclosed chamber", as used in the '057 patent claims, to mean a chamber that is completely closed on all sides. We further interpret the term "support attached inside the dectector chamber" to mean a support that is entirely inside the detector chamber. Finally, we interpret the term "removable portion of a detector wall" to mean a structure that is capable of functioning as part of a wall of a completely enclosed detector chamber.

55/ TR 525.

56/ CX-4, Fig. 2a.

C. Literal Infringement

Literal infringement is established if an accused structure falls clearly within the language of the patent claim. [57/] Respondents concede that their devices contain all of the elements of claim 5 except a "completely enclosed chamber", "a support attached inside the chamber to mount a sample", and "at least a portion of one wall of the enclosed chamber [that] is removable". Complainant contends that respondents' devices have simply combined the sample holder and removable wall into one structure, and in use, the detector and sample holder of respondents' analyzers form a completely enclosed chamber. Thus, complainant contends that respondents' analyzers literally infringe the '057 patent.

The ALJ found that none of the devices at issue in this investigation had a completely enclosed chamber, [58/] internal support for holding samples, or a removable detector chamber wall. [59/] In view of our interpretation of the claims at issue and the evidence of record, we adopt those findings of the ALJ. We therefore determine that respondents' devices do not literally infringe claims 5, 8, or 9 of the '057 patent.

D. Infringement Under the Doctrine of Equivalents

Infringement under the doctrine of equivalents is established if an accused structure performs substantially the same function in substantially the same way to achieve substantially the same result as the claimed

---

57/ Graver Tank & Mfg. Co. v Linde Air Products Co., 339 U.S. 605 (1950).

58/ FF 280-282.

59/ FF 283-297.

invention. 60/ Equivalence is determined against the context of the patent, the prior art, and the particular circumstances of the case. 61/ While the doctrine can be used to expand the claims to cover more than would literally infringe, it cannot be used to expand the patent claims to cover what was in the prior art, 62/ or what was given up by the inventor during prosecution at the PTO. 63/

The range of equivalents to which a patent claim is entitled depends on whether the patent is a pioneer patent, a small improvement, or something in between. 64/ The ALJ determined that the '057 patent was a minor improvement patent that was entitled to only a narrow range of equivalents. 65/ We adopt the ALJ's determination concerning the '057 patent's range of equivalents.

Respondents' devices analyze samples that are placed outside the detector chamber. 66/ The patent documents do not suggest that the '057 invention encompasses devices that analyze samples placed outside the detector chamber.

60/ Graver Tank, 339 U.S. at 608.

61/ Id. at 609

62/ Carman Industries v. Wahl, 724 F.2d 932, 942, 220 U.S.P.Q. 481, 489 (Fed. Cir. 1983)

63/ Autogiro Co. of America v. United States of America, 384 F.2d 391, 398-399, 155 U.S.P.Q. 697, 703-04 (Ct. Cl. 1967).

64/ Autogiro, 384 F.2d at 401, 155 U.S.P.Q. at 705.

65/ ID at 48.

66/ FF 284-285.

Indeed, several passages in the '057 specification specify placing the sample to be analyzed within the detector chamber. 67/ Moreover, during the original examination of the '057 patent, the Insitut Pasteur's (the assignee) attorney stated in response to a rejection made under 35 U.S.C. § 112:

> placement of a solid object within the chamber of a position-sensitive radiation detector [is an] important aspect of the applicant's invention. 68/

Prosecution history estoppel prevents complainant from expanding the '057 claims under the doctrine of equivalents to cover respondents' analyzers. In response to a prior art rejection given by the PTO during the examination of the '057 patent, the Institut Pasteur attorney distinguished the '057 claims over a prior art reference by arguing that the '057 claims required the sample to be placed inside the detector chamber. 69/ Thereafter, the patent examiner withdrew the prior art rejection, and the '057 patent issued. By

---

67/ These passages include:

> The present invention is related to a method and apparatus for determining the spatial distribution of radioactivity in an object, and more particularly to an arragement for enclosing the object inside the detector. CX-4, Col. 1, lines 6-10.
>
> Placing the radioactive object inside the detector eliminates the need for a window and permits such double labled experiments. CX-4, Col. 3, lines 5-8.
>
> In accordance with these objects, efficient counting of low energy particles and a determination of their spatial distribution with a high spatial resolution is enabled by placing the object inside the detector chamber. CX-4, Col. 4, lines 29-34.

68/ CX-1, Response to Office Action of January 7, 1976 at 5. See also FF 313.

69/ FF 305-308.

responding in such a manner to the prior art rejection, the assignee's attorney forfeited coverage of devices that place the sample to be analyzed outside the detector chamber. 70/

E. Conclusion As To Infringement

The record in this investigation clearly supports a finding that gas flow chromatogram analyzers, such as those of complainant and respondents, which operate with a gap between the detector and sample, cannot be considered to fall within the scope of the '057 claims, either literally or under the doctrine of equivalents. Therefore, we find no infringement in this investigation.

VI. Domestic Industry

The Commission defines the domestic industry in patent, trademark, and copyright cases as the domestic operations of complainant that are devoted to the exploitation of the intellectual property right at issue. 71/ We determine that complainant is not exploiting the '057 patent because complainant's chromatogram analyzers lack the following elements of claim 5 of the '057 patent: (1) a completely enclosed chamber, (2) a portion of one chamber wall that is removable, and (3) a sample holder or support inside the chamber. The Commission therefore determines that because complainant is not

---

70/ See e.g. Autogiro, 384 F.2d at 398-399, 155 U.S.P.Q. at 703-04.

71/ See, e.g., Certain Cloisonne Jewelry, Inv. No. 337-TA-195, USITC Pub. 1822 (March 1986); Certain Foam Earplugs, Inv. No., 337-TA-184, USITC Pub. 1671 (March 1985); Certain Drill Point Screws For Drywall Construction, Inv. No. 337-TA-116, USITC Pub. 1365 (March 1983).

practicing the '057 patent no domestic industry exists in this investigation. 72/

VII. Conclusion

Based on the foregoing, we determine that claims 5 and 8 of the '057 patent are valid, but not infringed by respondents. We have adopted those parts of the ID finding that complainant's operations are efficiently and economically operated and that complainant's operations have been injured by respondents' activities. We determine, however, that complainant's operations do not constitute a domestic industry because complainant is not exploiting the patent at issue. Because we have found no unfair act and no domestic industry in this investigation, we determine that there has been no violation of section 337.

72/ Certain Stabilized Hull Units and Components Thereof and Sonar Units Utilizing Said Stabilized Hull Units, Inv. No. 337-TA-103, USITC Pub. No. 1260 (June 1982).

CERTIFICATE OF SERVICE

I, Kenneth R. Mason, hereby certify that the attached NOTICE OF TERMINATION OF INVESTIGATION ON THE BASIS OF NO VIOLATION OF SECTION 337 OF THE TARIFF ACT OF 1930, was served upon Jeffrey L. Gertler, Esq., and Cheri Taylor, Esq., and upon the following parties via first class mail, and air mail where necessary, on July 16, 1987.

Kenneth R. Mason, Secretary
U.S. International Trade Commission
701 E Street, N.W.
Washington, D.C. 20436

FOR COMPLAINANT BIOSCAN, INC.:

Frederick G. Michaud, Jr., Esq.
Eric H. Wiesblatt, Esq.
Burns, Doane, Swecker and Mathis
George Mason Building
Washington and Prince Streets
Alexandria, Virginia 22313-1404

RESPONDENTS

FOR ALOKA CO., RADIOMATIC INSTRUMENTS & CHEMICAL CO., INC.:

Mr. Andrew R. Reich
President
Radiomatic Instruments and Chemical Co., Inc.
5102 S. Westshore Boulevard
Tampa, Florida 33611

FOR ISOTOPENMESSEGERATE GmbH:

Dr. Edward Rapkin
President
IN/US SERVICE CORPORATION
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

GOVERNMENT AGENCIES:

Mr. Charles S. Stark
Antitrust Div./U.S. Dept of Justice
Room 7115, Main Justice
Pennsylvania Avenue & Tenth Street, N.W.
Washington, D.C. 20530

Edward F. Glynn, Jr., Esq.
Assistant Director(International)
Bureau of Competition
Federal Trade Commission
Room 2636
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Darrel J. Grinstead, Esq.
Dept of Health and Human Svcs.
Room 5362, North Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Michael T. Schmitz
Chief Counsel
U.S. Customs Service
1301 Constitution Avenue, N.W.
Washington, D.C. 20229

PUBLIC INSPECTION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of CERTAIN ELECTRONIC CHROMATOGRAM ANALYZERS AND COMPONENTS THEREOF	Investigation No. 337-TA-251

INITIAL DETERMINATION

Administrative Law Judge Sidney Harris

APPEARANCES

For Bioscan Inc.:

Frederick G. Michaud, Jr., Esq.
Eric H. Weisblatt, Esq.
BURNS, DOANE, SWECKER & MATHIS

For Aloka Co.; Radiomatic Instruments & Chemical Co. Inc.:

Andrew R. Reich
President
RADIOMATIC INSTRUMENTS AND CHEMICAL CO. INC.

For Isotopenmessgerate GmbH; IN/US Service Corporation:

Edward Rapkin
President
IN/US SERVICE CORPORATION

For United States International Trade Commission:

Jeffrey Gertler, Esq.
Cheri Taylor, Esq.

TABLE OF CONTENTS

PAGE

OPINION (Continued)

PAGE

FINDINGS OF FACT (Continued)

PAGE

FINDINGS OF FACT (Continued)

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of CERTAIN ELECTRONIC CHROMATOGRAM ANALYZERS AND COMPONENTS THEREOF	Investigation No. 337-TA-251

INITIAL DETERMINATION
Sidney Harris, Administrative Law Judge

Pursuant to the Notice of Investigation, 51 Fed. Reg. 24945-46 (July 09, 1986), this is the administrative law judge's Initial Determination in the Matter of Certain Electronic Chromatogram Analyzers and Components Thereof, U.S. International Trade Commission Investigation No. 337-TA-251. 19 C.F.R. § 210.53(a).

The administrative law judge hereby determines that there is no violation of section 337 of the Trade Act of 1930, as amended, 19 U.S.C. § 1337, in the importation of certain chromatogram analyzers, or in their sale, by reason of infringement of claims 5, 8 and 9 of U.S. Letters Patent No. 4,019,057 (Bram) (the '057 patent), the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States.

OPINION

I. PROCEDURAL HISTORY

By publication in the Federal Register on July 9, 1986, the Commission gave notice of the institution of an investigation under section 337 of the Tariff Act of 1930, pursuant to a complaint filed by Bioscan, Inc., a corporation of the District of Columbia, to determine whether there is a violation of subsection (a) of section 337 in the unlawful importation of certain electronic chromatogram analyzers and components thereof into the United States, or in their sale, by reason of alleged direct, contributory, and induced infringement of claims 5, 8, and 9 of U.S. Letters Patent 4,019,057 (the '057 patent), the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States. 51 Fed. Reg. 24945 (July 9, 1986). The Commission named Bioscan, Inc., as the complainant, and the following companies as respondents:

Isomess, Isotopenmessgerate GmbH ("Isomess")
Federal Republic of Germany

Aloka, Co. ("Aloka")
Tokyo, Japan

Radiomatic Instrument & Chemical Co., Inc. ("Radiomatic")
Tampa, Florida

IN/US Service Corporation ("IN/US")
Fairfield, New Jersey

Counsel entered appearance for the above-named respondents, and filed answers to the complaint and notice of investigation on their behalf. Counsel for respondents later withdrew, and respondents made known their intention to proceed without counsel represented by principals of IN/US and Radiomatic. Dr. Edward Rapkin entered appearance for Isomess and IN/US; Mr. Andrew Reich entered appearance for Aloka and Radiomatic.

Chief Administrative Law Judge Janet D. Saxon designated Administrative Law Judge Sidney Harris to preside over this investigation.

A Preliminary Conference was held in this investigation on August 14, 1986. Appearances were made on behalf of complainant Bioscan, Inc.; respondents Isotopenmessgerate GmbH, Radiomatic Instruments & Chemical Co., Inc., Aloka Co., and IN/US Service Corporation; and the Commission Investigative Staff. The prehearing and hearing schedule for this investigation was set at this time. Order No. 5 (August 15, 1986). The schedule was amended on December 11, 1986. Order No. 6.

On December 24, 1986, respondents filed a motion to amend their notification of prior art to include an additional document respondents stated they found for the first time on December 22, 1986. Motion Docket No. 251-3. On January 8, 1987, the administrative law judge granted the respondents' motion. Order No. 7.

A telephonic Prehearing Conference was held before Administrative Law Judge Sidney Harris on January 16, 1987. Appearances were noted for the record by complainant Bioscan, Inc., all respondents, and the Commission Investigative Staff. The hearing in the matter of Certain Electronic Chromatogram Analyzers and Components Thereof commenced on January 27, 1987 and concluded on January 30, 1987.

This Initial Determination is based on the entire record of this proceeding. Proposed findings not herein adopted, either in form or in substance, are rejected as not being supported by the evidence or as involving immaterial matters.

The findings of fact include references to supporting evidentiary items in the record. Such references are intended to serve as guides to the depositions, exhibits, and testimony supporting the findings of fact; they do not necessarily represent complete summaries of the evidence supporting each finding. Some of the findings of fact are contained only in the opinion.

The following abbreviations are used in this Initial Determination:

CX- Complainant's Exhibit (followed by its number and the reference page(s)).

CRX- Complainant's Rebuttal Exhibit.

CPX- Complainant's Physical Exhibit.

RX- Respondents' Exhibit.

RRX- Respondents' Rebuttal Exhibit.

RPX- Respondents' Physical Exhibit.

SX- Staff Exhibit.

SRX- Staff Rebuttal Exhibit.

SPX- Staff Physical Exhibit.

ALJX- Administrative Law Judge Exhibit.

FF- Finding of Fact.

Dep.- Deposition.

Tr.- Transcript.

II. INTRODUCTION

A. Background

There are various configurations of devices designed to detect low-energy radioactivity in an object. The detector chambers in all said devices are filled with gas and an electric field set up by an anode and cathode. FF 39a, 40. The decay of a radioactive substance results in the emission of a low-energy electron or beta particle. FF 37. Electrons are freed also by "gas multiplication," which is the freeing of more electrons by the collision of already freed electrons with additional gas molecules as the former are attracted to the anode. FF 39, 44. The kinetic energy of the collisions frees electrons from the molecules and thus ionizes them. FF 36, 37. The presence of low-energy radiation is detected by measuring the ionization of a gas resulting from the entry of the beta particles into the sensitive volume of the gas, by the anode within the gas volume. FF 39a. Electrons are attracted to the anode and, as they impinge upon it, a signal is produced by the electronics attached to the detector. FF 45. By operating the detector in the range of 1200 to 1700 volts, the signal produced is proportional in amplitude to the amount of ionization of the gas caused by the radioactivity. FF 42, 43. Use of a high-resistance wire for the anode or other electronics makes it possible for a proportional detector to determine the position of a radioactivity decay event in a sample that is measured. FF 45, 124.

Early detectors of radioactivity involved placing the object to be analyzed in a gas tight or sealed chamber. FF 90-91, 97-100. However, this method presented several undesirable and costly features, stemming from the contamination of the chamber each time an object was placed inside and taken out. FF 69. For high energy radioactivity a solution was to place the object to be analyzed outside a closed window of the detector chamber. FF 91a. The window refers to a wall or part of a wall of the detector chamber constructed of a material which would permit the radioactivity to pass through it. Id. Although this was satisfactory for high energy isotopes, it was unsatisfactory for low energy emitters, used in medical and biological research, since such emissions could not penetrate even the thinnest windows. RX 27; FF 114. Consequently, windowless detectors were designed. Instead of a window constructed of metal or plastic, a slit was cut into one of the walls of the detector chamber, and the sample to be analyzed would be placed just outside the chamber so that the ionizing gas and electric field completely covered the surface of the sample by coming through the slit, and driving all contaminating air away from the sample. Low energy radiation, such as from tritium, would otherwise have been absorbed by the material of which the window was made. RX 27. In this way, even low energy tritium would be detected on the anode without the inconvenience of placing it for analysis in a sealed chamber. FF 106. Such devices are referred to as windowless flow counters. FF 114, 116.

B. Patent Office History

On February 26, 1975, Stanley Bram filed for a U. S. patent for a device for determining the spatial distribution of radioactivity within an object. In doing so, he claimed priority under his French patent application dated April 25, 1974. FF 10. The patent was initially refused. Claims 1, 2, and 5 through 10 were denied as being obvious over the Borkowski '377 patent in view of the Pocock '051 and Lovelock '135 patents, the examiner stating:

"The only difference between ['377] and system claimed is the placing of the measuring object within the chamber. ['051] and ['135] show that it is old to place radioactive material within a chamber for testing and measuring. It is considered obvious to place objects within a sealed chamber for the same purpose as claimed. Furthermore, holder for such object within the chamber is a necessity and collimator for directing radiation is so old that would be obvious modifications in the system of ['377 in view of '051 and '135]."

CX-1, Form PO-1142, p. 2, dated October 16, 1975 (33d page into exhibit).

The examiner also refused a patent on the grounds that the combination of claims was old in light of the Borkowski '377 patent and the 1973 Kaplan article which disclose the same elements in the same manner producing substantially the same results. The patent was also refused on the grounds that the specification was not sufficiently definite. CX 1, Form PO-1142, at 1, dated October 16, 1975 (32d page into exhibit).

Counsel for Mr. Bram successfully traversed the rejection, stating that the Bram device differed from '051 and '135 in that the object is placed in the chamber for purposes of analysis, not ionization, and the rejection was withdrawn. CX 1, Response to Office Action, at 8, dated May 4, 1976 (24th page into exhibit). U. S. Patent No. 4,019,057 was issued on April 19, 1977. FF 8, 9.

On March 1, 1983, Bioscan, Inc., the exclusive U.S. licensee of the Bram device, initiated a complaint under § 337 of the Tariff Act of 1930 as amended. CX 2, Inv. No. 337-TA-142. The investigation was terminated when

Laboratorium Prof. Dr. Berthold ("Berthold"), one of the respondents, agreed to a sublicense from Bioscan. Berthold agreed to the payment of royalties if certain claims were confirmed valid in a reexamination of the Bram patent. CX 2, Proposed Termination Agreement, at 4. On July 14, 1983, Berthold requested the reexamination in light of the prior art publications of Pullan et al., Kaplan et al. and Prydz. The examiner on reexamination rejected the claims of the Bram patent for obviousness. CX 2. Counsel for Mr. Bram appealed the rejection, pointing out that the new prior art discussed spark chambers and proportional chambers for high-energy particles. CX 2, Response to Office Action dated March 12, 1984, at 7. A certificate affirming the validity of the Bram patent was issued November 20, 1984. CX 2.

III. PATENT VALIDITY

A. Anticipation of the Bram Patent

1. 35 U.S.C. § 102(a).

The claims of a patent are invalid if "the invention was known or used by others in this country or patented or described in a printed publication in this or a foreign country before the invention thereof by the applicant." 35 U.S.C. § 102(a).

For a particular document to be a "printed publication" which anticipates a claim for purposes of § 102(a), there must be a satisfactory showing that it has been disseminated or otherwise made available to the extent that persons interested in and of ordinary skill in the subject art can locate it, and recognize and comprehend therefrom the essentials of the claimed invention -- without need of further research or experimentation. In re Wyer, 655 F.2d 221, 226 (CCPA 1981), Carella v. Starflight Archery, 804 F. 2d 135 (Fed. Cir. 1986). The description must be so detailed as to allow the skilled person to replicate the device. Preemption Devices v. Minnesota Mining and Manufacturing, 559 F. Supp. 1250, 218 U.S.P.Q. 245 (E.D. Pa. 1983) aff'd 732 F.2d 903, 221 U.S.P.Q. 841 (Fed. Cir. 1984) The publication must contain all the elements of the claimed invention as arranged in the claim. Connell v. Sears & Roebuck Co. 220 U.S.P.Q. 193, 198 (Fed. Cir. 1983).

Respondents contend that a 1971 scientific article (De Lima and Pullan, "A Position Sensitive Geiger Counter," (CX 77; RX 23)) contains all the elements of claim 5 of the Bram patent. (Respondent's Pre-Hearing Brief at 10). The specification language of the Bram patent calls for the measurement of relative pulse heights on the detector wire. CX 4, col. 7, lines 37-68. The claims in a patent are to be construed in light of the specifications as a whole, ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572 (Fed. Cir. 1984). Therefore, the apparatus described in claim 5 of the Bram patent is a position sensitive proportional counter capable of measuring relative pulse heights. The De Lima-Pullan article describes a position sensitive Geiger-Muller counter which is incapable of pulse-height discrimination. FF 83. Since the De Lima - Pullan article does not contain the pulse-height discrimination element of claim 5, it does not anticipate the claim.

Respondents further contend that each of certain position sensitive proportional counters built by C. J. Borkowski and M. K. Kopp anticipate claim 5 and that one of them anticipates claim 9. Respondents' Prehearing Br. at 10-11. In order to invalidate a patent on the grounds of anticipation by prior knowledge or use by others, a party must prove by clear and convincing evidence that the prior device had been completed, reduced to practice, and successfully performed. Ludlow Corp. v. Textile Rubber & Chemical Co., Inc., 636 F. 2d 1057 (5th Cir. 1981). Reduction to practice requires that the invention be sufficiently tested to demonstrate that it will work for its intended purpose. General Electric Co. v. United States, 654 F. 2d 55 (Ct. Cl. 1981). It must also be proven that the prior knowledge or use was accessible to the public. Gayler v. Wilder, 51 U.S. 476 (1850). The Borkowski-Kopp counters were devised as part of the experimental work performed at Oak Ridge National Laboratories (ORNL). While there is evidence that persons skilled in the art occasionally visited the ORNL laboratories to look at new devices and ask questions about them (FF 187), the record does not show by clear and convincing evidence that these counters were sufficiently publicly accessible to constitute prior knowledge or use for purposes of § 102(a).

Messrs. Borkowski and Kopp presented papers describing the results of experiments with the counters in 1970 and 1972. RX 39, 40. In addition, the work performed in developing these counters was reported in the 1971 Annual Progress Report from the Instrumentation and Controls Division of ORNL. RX 41. These reports do not provide sufficient detailed information which would allow a person skilled in the art to construct one of the Borkowski-Kopp position sensitive proportional counters. Therefore, they do not meet the definition of "printed publication" for purposes of § 102(a). Preemption Devices, supra. As such, these Borkowski-Kopp counters cannot be considered anticipatory prior art under § 102(a).

2. 35 U.S.C. § 102(g).

Respondents also contend that the Bram patent is invalid under 35 U.S.C.§ 102(g) which provides that an applicant is not entitled to a patent if, before his invention thereof, the invention was made in this country by another who had not abandoned, suppressed, or concealed it. Unlike § 102(a), this provision does not require that the prior invention be public, only that it be complete, i.e., conceived and reduced to practice. International Glass Co., Inc. v. United States, 408 F. 2d 395, 159 U.S.P.Q. 434 (Ct. Cl. 1968). However, courts have found an invention to be abandoned, suppressed, or concealed if no steps were taken to make the invention publicly known within a reasonable time after completion. Thus, failure to file a patent application; to describe the invention in a publicly disseminated document; or to use the invention publicly; have been held to constitute abandonment, suppression or concealment. Id. at 441 (citations omitted); Young v Dworkin, 489 F.2d 1277 (CCPA 1974). A party challenging a patent's validity under § 102(g) must prove by clear and convincing evidence that abandonment, suppression or concealment did not occur. Connin v. Andrews (P.O. Bd. Pat. Inter. 1984), 223 U.S.P.Q. 243.

At the hearing, Mr. Kopp testified that work he had performed at ORNL in 1970 and 1971 in connection with building devices for chromatography was abandoned in 1971 and not resumed until 1980. Kopp, Tr. 654. The technical papers mentioned above (RX 39 and RX 40) described the results of experiments, but did not describe the apparatuses used in sufficient detail for a skilled artisan to replicate them. Therefore, they are insufficient evidence that the invention was not abandoned, suppressed or concealed. Respondents did not present any evidence of further publicity concerning these particular counters. For a period of at least nine years, the work "lay dormant, did not enrich the art, and thus 'remained secret, effectively concealed and suppressed...'" International Glass at 441 quoting Carter Products v. Colgate-Palmolive Co., 130 F. Supp. 557, 104 U.S.P.Q. 314 (D. Md. 1955).

Accordingly, there is insufficient evidence that the Borkowski-Kopp counters anticipated the Bram patent under 35 U.S.C. § 102(g).

B. Obviousness of the Bram Patent

Respondents contend claims 5, 8, and 9 of the Bram patent are obvious over the prior art, including certain prior art patents and publications more pertinent than those considered by the patent examiner during both the original prosecution and reexamination of Bram. Respondents Post Hearing Br.

at 14. The statutory presumption of validity requires that respondents prove the obviousness of the Bram invention by clear and convincing evidence. 35 U.S.C. § 282.

Under 35 U.S.C. § 103, a patent may not be obtained if the claim is obvious over the prior art. Section 103 provides, in pertinent part, as follows:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains ....

The test for obviousness was set forth by the United States Supreme Court in Graham v. John Deere Co., 383 U.S. 1 (1966).

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. ... Such secondary considerations as commercial success, long felt but unresolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.
>
> Id. at 14-15

1. Scope and content of the prior art.

The question of obviousness must be resolved with reference to the time the invention was made. 35 U.S.C. § 103. Generally, "prior art" consists of all patents, publications, and prior uses which have been in existence prior to the date of invention of the patentee, or more than one year prior to his filing date. 35 U.S.C. § 103; Mohasco Industries, Inc. v. E. T. Barwick Mills, Inc., 221 F. Supp. 191 (N.D. Ga., 1963), aff'd 340 F.2d 319 (5th Cir. 1965), rhrng denied, 342 F.2d 431 (5th Cir. 1965), cert. denied, 382 U.S. 847 (1965).

Under 35 U.S.C. § 119, a patentee may receive the benefit of the date of an earlier filing on his behalf for the same invention in a foreign country. The United States filing must occur within one year of the foreign filing and the foreign country must provide reciprocal treatment to United States filings. Further, certain procedural requirements must be met. 35 U.S.C. § 119.

On April 25, 1974, Dr. Bram filed French patent application No. 74.14453. FF 10. A U.S. application for this invention was filed on February 26, 1975, and U.S. Patent No. 4,019,057 (the Bram patent) was issued on April 19, 1977. FF 8, 9. The parties have stipulated that the Bram U.S. Patent is based upon the French priority application filed April 25, 1974. CX 164, Stipulation 10. Therefore, the date of invention for purposes of determining obviousness is April 25, 1974.

The scope of the prior art is best defined in terms of the nature of the problem to be solved. Orthopedic Equipment Co., Inc. v. United States, 702 F.2d 1005 (Fed. Cir. 1983). One of ordinary skill in the art may be presumed to have knowledge of arts reasonably pertinent to the particular problem with which the inventor was involved. Pentec, Inc. v. Graphic Controls Corporation, 227 U.S.P.Q. 766 (Fed. Cir. 1985). In the suit patent, the inventor sought to solve the problem of measuring the spatial distribution of low energy radioactive particles within an object quickly and with improved resolution. FF 74. Thus, the ordinary person skilled in the relevant art would have looked to patents and other art concerning radiation detection devices.

The art related to the claims at issue fall into four different categories of radioactivity measuring devices. There are the conventional (non-position-sensing) proportional counters which teach the placement of radioactive samples, including low-energy samples such as ^{14}C and ^{3}H, <u>inside</u> a gas-tight detector chamber for measurement of the level of radioactivity from said samples. After the insertion of the sample the chamber is completely enclosed except for means to introduce gas. RX 29; FF 90-102. The second category covers conventional proportional counters which teach the placement of radioactive samples, including low-energy samples such as ^{14}C and ^{3}H, <u>outside</u> a detector chamber but in close proximity to a windowless opening (slit) in one wall of the chamber, so that the electric field and the ionizing gas flow over the samples, permitting measurement of the level of radioactivity in said samples. RX 15, 17; FF 103-17. The third category includes position-sensing electronics in combination with the above conventional proportional counters for operation as position sensitive proportional counters, which can locate the position of the radioactive event in the sample. RX 1, 16; FF 118-23. The fourth and final category relates to multi-wire proportional counters giving position sensing on a two- or three-dimensional basis. RX 7, 8; FF 124-29.

In attacking the validity of the <u>Bram</u> patent, respondent and staff assert that the PTO erred in not considering certain alleged prior art, consideration of which would have resulted in the rejection of claims 5, 8, and 9 of the Bram patent on the grounds of obviousness. Respondents Post Hearing Br. at 14, Commission Investigative Attorney's Post Hearing Br. at 8.

Each claim of a patent is presumed valid. 35 U.S.C. § 282. This statutory presumption flows from a congressional assumption that the PTO properly performs its administrative functions including a thorough scrutiny of prior art references. E.I. duPont de Nemours & Co. v. Berkley & Co., Inc., 205 U.S.P.Q. 1 (8th Cir. 1980). The assumption that the PTO properly performed this scrutinizing function can be destroyed by demonstrating that the examiner did not consider pertinent prior art which is in one of the patent subclasses searched. The search record as indicated on the "file wrapper," i.e., prosecution history, of a patent application is prima facie evidence that a patent examiner has considered all the references classified in the classes and subclasses searched, citing only the most relevant references. Thus, the presumption of validity may be partially or wholly overcome when a party shows by clear and convincing evidence that certain prior art was not considered by the patent examiner. American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360 (Fed. Cir. 1984).

With regards to the first category (proportional counters with the sample inside the detector), the prosecution history of the Bram patent indicates that the PTO did not consider U.S. Patent No. 2,590,925 for a "Proportional Counter" issued to Borkowski and Fairstein on April 15, 1952. The examiner initially rejected claim 5 of the Bram patent under 35 U.S.C. § 103 as being obvious over U.S. Patent 3,783,377 to Borkowski (RX-1) in view of U.S. Patent 3,008,051 to Pocock and U.S. Patent 3,176,135 to Lovelock, it being old to place an object in the chamber. CX 1. In doing so, the examiner noted that the only difference between the '377 patent (in view of the Pocock and Lovelock references) and the Bram patent was the placing of a radioactive object within the chamber for testing and measuring. Id. In seeking a withdrawal of this rejection, the prosecuting attorney argued that Pocock and Lovelock were not relevant prior art since they taught the placement of a radioactive object for purposes of ionizing the gas within the chamber. In contrast, they argued, claim 5 teaches the placement of the radioactive object in the chamber for purposes of analyzing the object itself and this teaching, counsel stated, was not old. CX 1. After considering this argument, the patent examiner withdrew his rejection of claim 5. CX 1, Index of Claims, page 2 of Exh.

Complainant, citing E.I. duPont De Nemours & Co. v. Berkley & Co., Inc., supra., asserts that the Borkowski-Fairstein '925 patent (along with other references in the first category of prior art) falls within one of the subclasses of patents searched by the examiner, and that it is to be presumed that it was considered when the Bram patent was issued. Complainant's Post Hearing Br. at 14.

In Lindemann Maschinefabrik GMBH v. American Hoist & Derrick, 221 U.S.P.Q. 481 (Fed. Cir. 1984), the Federal Circuit stated that the presumption that the examiners had considered uncited art which is within the classes and subclasses searched is overcome by showing that the uncited art is more pertinent than that cited. 221 U.S.P.Q. at 486-87. The Pocock and Lovelock patents teach the placement of a radioactive source within the detection chamber for the purpose of ionizing the gas. CX 1. By contrast, the '925

Borkowski-Fairstein patent teaches the placement of a low-energy radioactive object within a proportional detector chamber for the purpose of analyzing the object. RX 3. The '925 patent teaches precisely what the applicant said was new, and which led to the withdrawal of the rejection. Thus, it is more pertinent to the validity of Bram than the Pocock and Lovelock references. FF 177. Applying the rule laid down in Lindemann, this relatively greater pertinence overcomes the presumption that the examiner considered the '925 patent and other similar prior art when determining the validity of claim 5.

The second category of prior art relates to windowless proportional counters. These were developed for the measurement of low energy radioactive emitters, because of the inconvenience of using the completely enclosed box of the category one prior art. RX 17; FF 69. They involve a slit carved in one side of the detector and the placement of the sample in close proximity to the opening, and are thus known as windowless proportional counters. Complainant contends that claim 5 of the Bram patent, under the doctrine of equivalents, should be read broadly to cover these products. Complainant's Post Hearing Br. at 26.

The record of the prosecution and reexamination of the Bram patent reflects that the patent examiner did not consider the large body of prior art related to windowless proportional counters when determining the validity of claim 5. CX 1, 2. This body of prior art includes U.S. Patent No. 3,603,831 awarded to Hermann Kimmel (RX 27) and the 1962 article by Schulze and Wenzel (RX 17). Yet, functionally these windowless gas-flow detectors detect radioactivity in the same manner as the completely enclosed radiation detectors exemplified by the Borkowski-Fairstein '925 patent. Polic, Tr. 576-77. They are thus more pertinent than the Pocock, Lovelock and Dimick patents which merely exemplify uses of radioactivity in a chamber for ionization.

Items in the third category of prior art teach the modification of both sealed and windowless flow counters for operation as position sensitive proportional counters by the insertion of a high resistance electrode into the chamber. An example of this prior art is the Borkowski '377 patent which teaches the insertion of a high resistance collector into the gas chamber. FF 118. This procedure is also described in several scientific articles which predate the invention of the Bram patent. FF 122, 122a, 122b. Items in this category were considered by the examiner who cited the Borkowski '377 patent as a reference when issuing the Bram patent. CX 4.

The final category of prior art is exemplified in an article by Kaplan et al., entitled "Multi-wire Proportional Chambers for Biomedical Applications," Nuclear Instruments and Methods (1973) which describes multi-wire proportional counters incorporating the delay-line electronics necessary for position sensitivity in more than one dimension. FF 124. A multi-wire proportional counter is also taught by U.S. Patent 3,786,270 issued to Borkowski and Kopp on January 15, 1974. FF 126. Other such counters are discussed in several scientific articles which predate the Bram patent. FF 127, 128, 129. The Kaplan article was cited as a reference on both prosecution and reexamination of the Bram patent. CX 2, 4.

Claim 8 discloses and claims the use of a mechanical collimator between the sample and the detector anode wire to improve resolution.[1/] FF 142. The prior art teaches the use of mechanical collimators for improving the resolution of proportional counters. FF 135. Mechanical collimation for position sensitive proportional counters is disclosed in the 1973 Kaplan article (FF 138) and was referenced by the examiner during the prosecution and reexamination of the Bram patent. CX 1, 2. Mechanical collimation is also disclosed in the Borkowski-Kopp '270 patent and in an article published by Borkowski and Kopp in 1972. FF 137; RX 40. A 1973 brochure for The Packard Model 7201 Radiochromatogram Scanner also illustrates the use of mechanical collimators. FF 140. During prosecution the examiner found that such collimation was very old in the art. CX 1.

Claim 9 of the Bram patent discloses the use of electronic collimation through the use of a selection circuit that utilizes pulse-height discrimination to prevent the display of data of particles not travelling at an angle substantially perpendicular to the object. FF 143. The prior art relating to proportional counting also teaches electronic collimation through pulse-height discrimination. During the reexamination, the examiner also found electronic collimation to be old in the art. CX 2. In addition, the 1972 IEEE Transactions paper by Borkowski and Kopp entitled "Proportional Counter Photon Camera" discloses the use of "energy discrimination" to improve resolution of the image in a proportional counter. FF 130.

2. Combination of prior art.

Unlike anticipation under § 102, obviousness can be proven by combining several prior art references. However, in such instances the party

---

1/ Beta particles are isotropic, i.e., they radiate equally in all directions. FF 63.

challenging the validity of the patent must prove there is some teaching, suggestion, inference, or knowledge generally available to one of ordinary skill in the relevant art which would have led him to combine the relevant teachings. Ashland Oil Inc. v. Delta Resins & Refractories, Inc., 227 U.S.P.Q. 657, 664 n.24 (Fed. Cir. 1985). A suggestion to modify the art to produce the claimed invention need not be expressly stated in one or all of the references used to show obviousness. Cable Electric Products, Inc. v. Genmark, Inc., 770 F.2d 1015, 1025 (Fed. Cir. 1985). The proper approach to the question of whether references are to be combined is "whether the hypothetical person of ordinary skill in the relevant art, familiar with [the prior art], would have found it obvious to make a structure corresponding to what is claimed." In re Sovish, 226 U.S.P.Q. 771, 774 (Fed. Cir. 1985) (citations omitted).

The prior art related to position-sensitive electronics contains the requisite teaching, suggestion, or inference that would lead one who is skilled in the art of radiation detection and familiar with the prior art to combine it with gas-filled detectors for analyzing low energy radioactivity. The clearest such teaching is the Borkowski-Kopp '377 patent for position-sensing electronics. The specification explicitly states that the device "is applicable to many detectors, including both gas and semiconductor types. . . . The position-sensitive gas-filled detector, described hereinafter as an illustration of this invention, is more sensitive to low energy ionizing particles and has improved spatial resolution." RX 1, col. 3, lines 2-8. To one skilled in the art of radiation detection technology and seeking to convert a proportional gas-filled detector so as to make it position-sensitive, the Borkowski-Kopp '377 patent would make the solution to the problem obvious. Teachings also appear in Borkowski and Kopp's 1970 IEEE article (RX 39) in which they describe the results of their experiments with this position-sensitive gas-filled detector. Borkowski and Kopp's 1970 IEEE article describes the use of position-sensing electronics with gas-flow detectors as well. RX 39 at 343. See generally, FF 164-74.

3. Differences between Bram patent and prior art.

In determining obviousness, it is not the differences between the claimed invention and the prior art that is in question, but rather it is the consideration of those differences in determining whether the claimed invention as a whole would have been obvious to one of ordinary skill in the art. Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1537 (Fed. Cir. 1983).

The Bram detector is designed to operate at beyond atmospheric pressure for improved spatial resolution. FF 79. It is a modification of Kaplan (RX 25), and is designed to detect beta particle radiation under pressure with improved resolution. CX 4, col. 6, lines 33-37. Kaplan described a multiwire proportional counter operating at pressures beyond atmospheric level for detecting gamma ray and X-ray radiation with improved resolution. The position-sensing windowless flow counters are designed to operate only at atmospheric pressure. Rothberg, Tr. 409. The completely enclosed detectors of the '925 Borkowski type (RX 3) are designed to be gas tight, but do not teach operation at beyond atmospheric pressure for improved spatial resolution. Position sensing electronics are acknowledged in Bram as prior art. See figure 1 of the Bram patent in which a position sensing circuit is labeled "Prior Art," (CX 4, fig. 1) and see also, the corresponding text (at col. 4, lines 50-51) where it is stated that fig. 1 "shows a prior art circuit for determining the spatial distribution of radioactivity in an object." The combination of position-sensing electronics with detectors was taught in the Borkowski '377 patent (RX 1) and specifically the position sensing electronics in combination with windowless proportional counters was disclosed in Borkowski and Kopp's 1970 IEEE article. RX 39. As indicated in the Bram patent, this combination was within the general knowledge of one skilled in the art of radiation detection in 1974.

With regards to the collimators disclosed in claims 8 and 9, they are old in the art. CX 2. However, the claims are dependent upon claim 5. FF 142-43. Where, as here, neither party argues separately the patentability of a dependent claim, the validity of the dependent claim will stand or fall with the underlying independent claim. In re Sernaker, 217 U.S.P.Q. 1, 3 (Fed. Cir. 1983). As such, claims 8 and 9 will be invalid for obviousness if claim 5 is obvious.

4. Level of ordinary skill in the art.

Obviousness is determined entirely with reference to a hypothetical person of ordinary skill in the art. Such a person is presumed to be aware of all the pertinent prior art but does not undertake to innovate. Standard Oil Co. v. American Cyanamid Co., 227 U.S.P.Q. 293, 297 (Fed. Cir. 1985). In determining the level of ordinary skill, factors such as the content of the prior art, the type of problems encountered in the art, and the educational background of those active in the field are considered. See Orthopedic Equipment Co., Inc. v. United States, 702 F.2d 1005, 1011-1012 (Fed. Cir. 1983).

An ordinary person skilled in this art in 1974 would have some educational background in physics, possibly only at an undergraduate level. Shulman Dep., RX 52 at 269-71. He or she would also have either experience or education in electrical technology. Shulman Dep., RX 52 at 269. Finally, this person would have been generally familiar with the various scientific journals related to the art of radiation detection devices. FF 186.

Evidence supporting a § 102 defense can be probative on the issue of the level of skill in the pertinent art even if it is inadequate to support the § 102 defense. Orthopedic Equipment Co., 702 F.2d at 1011. It is also probative of how those confronted with a similar problem at the time would have attempted to solve it. Del Mar Engineering Laboratories v. United States, 524 F.2d 1178, 1182-1183 (Ct. Cl. 1975). The testimony of Borkowski indicated that his work at ORNL in the early 1970's included the improvement of spatial resolution by various means, including pulse-height analysis. This work is indicative of the general level of skill in the art in April, 1974. FF 199.

Accordingly, a person of ordinary skill in the art of radiation detection in 1974 would have been familiar with the various types of radiation detectors such as gas flow counters, multi-wire proportional counters, closed chamber counters with the sample placed within the chamber, and closed chamber counters pressurized beyond atmospheric pressure for the detection of high-energy radiation. He would also have been familiar with the use of position-sensing electronics in combination with these counters. However, the prior art would not have taught such a person to utilize a chamber pressurized beyond atmospheric pressure for the detection of low-energy radiation. There is no indication that the utilization of such a chamber for detecting low-energy radiation was a part of the general level of knowledge in the art.

5. Secondary Considerations

Although certainly relevant to the test of nonobviousness, secondary considerations, such as commercial success, copying, long felt need, and failure of others may be invoked successfully only when considerable doubt exists over the issue of nonobviousness or when the secondary considerations are clear and unambiguous. The critical test under 35 U.S.C. § 103 is whether the invention as a whole would have been obvious to one of ordinary skill in the art at the time it was invented. Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 894-95, 221 U.S.P.Q. 669, 674 (Fed. Cir. 1984) cert. denied, 469 U.S. 857, 105 S. Ct. 187, 225 U.S.P.Q. 792 (1984). In Perkin-Elmer, the court cited strong, objective, and uncontested evidence to support a finding of nonobviousness.

Hardly determinative on their own, secondary considerations may be persuasive particularly when a claim is not clearly obvious. Given the economic and motivational underpinnings involved in any invention, objective evidence of nonobviousness is often useful in examining established facts. The Federal Circuit Court of Appeals recently found that the failure of the lower court to consider secondary considerations constituted grounds for reversal. Simmons Fastener Corp. v. Illinois Tool Works, 739 F.2d 1573 (1984), cert. denied, 471 U.S. 1065, 105 S. Ct. 2138 (1985). There, strong evidence of commercial success was held to be entitled to great weight. Id., at 1576.

a. The Nexus requirement.

Complainant contends that the factual evidence circumstantially supports a finding that the patented subject matter consists of imaging proportional counters or radiation detectors, and that such devices would not have been obvious to one of ordinary skill in the relevant art at the time of the claimed invention. (Complainant's Br. at 12). As shown above, the Bram patent itself, together with other substantial evidence of the prior art, clearly indicate that such devices were part of the prior art. However, we must examine the secondary consideration in light of complainant's argument. A sufficient nexus must be established between the merits of the claimed invention (as defined by complainant's counsel) and evidence of secondary considerations offered in support thereof. The court in Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1539 (Fed. Cir. 1983) established the notion that such a nexus must be present to warrant a finding of nonobviousness based upon commercial success or long felt, but unfilled, need.

When this standard is viewed in conjunction with the Supreme Court's ruling in Graham v. John Deere Co., 383 U.S. 1, 86 S. Ct. 684, 15 L.Ed.2d 545 (1966), complainant must establish that the commercial success of imaging chromatogram analyzers is due to Bram's invention. However, Graham requires that secondary considerations be viewed only as probative indicia of non-obviousness. As set forth recently by the Federal Circuit Court of Appeals in Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565 (1983):

> Requiring consideration of all evidence probative of a question is not the same as requiring that particular evidence must be controlling. . . . Objective evidence ("secondary considerations"), such as commercial success due to the merits of the invention, must when present be considered as part of the obviousness equation. Id., at 17.

b. Commercial success.

As set forth in a recent Federal Circuit Court of Appeals decision, data evidencing secondary considerations must apply to the invention as claimed. Pentec, Inc. v. Graphic Controls Corp., 776 F.2d 309, 317, 227 U.S.P.Q. 766 (Fed. Cir. 1985). In Pentec, the court found that the objective evidence was insufficient to overturn the lower court's finding that the claimed invention would have been obvious to one of ordinary skill in the art when it was made.

No evidence has been presented at trial establishing that sales of the Bram invention so dominated the market following the French priority application date, April 24, 1974, that a conclusion of nonobviousness based upon commercial success is warranted. Indeed, there is no documentary or testimonial evidence that a device was ever marketed or built by Bram. FF 219. Furthermore, the record does not establish the existence of a nexus between the Bram patent and the commercial success of respondents' devices. See, FF 230. Indeed, complainant has failed to establish that Bram's claimed invention was the catalyst for developing the imaging chromatogram analyzer market in the United States. See, FF 230. Thus, market sales of the complainant's and respondents' devices do not provide sufficient basis for a presumption of nonobviousness. Bram's closed chamber device, as disclosed in the specification, substantially differs from the devices presently marketed by Bioscan and respondents. Contrary to complainant's assertions, Bioscan's own commercial success in the chromatogram analyzer market was not the result of contact with Bram.

Dr. Shulman's contemporaneous research and development efforts produced Bioscan's commercial success. Shulman, Tr. 98-100; CPX 2, 3, 4. Dr. Shulman was not aware of research papers relating to the prior art on the detection of certain elements from chromatographic plates. Shulman, Tr. 296; FF 216. He was equally unaware of chromatography scientific literature throughout this time period, such as prior art publications by Berthold. Shulman, Tr. 286. Not until the summer of 1980 did Dr. Shulman and Bioscan sell a box-like commercial device of the Bram type to the National Institutes of Health. Shulman, Tr. 126. This model, however, proved to be unsaleable and respondent switched to its current imaging proportional gas flow counter. FF 217c. Therefore, as the court found in Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 1151, 219 U.S.P.Q. 857 (Fed. Cir. 1983), "the totality of the evidence is inadequate" to reach a finding of nonobviousness of the Bram patent.

c. Copying

Complainant seeks to establish that respondents' and Berthold's present chromatogram analyzer models originated from models constructed by Bram in France. In particular, complainant asserts that the devices at issue were developed from a 1976 technical assistance agreement between Institut Pasteur and a French company, Numelec, (CX 16), or from a 1977 secrecy agreement between Institut Pasteur and Laboratorium Berthold, a German company. CX 15. Although Numelec did receive certain technical assistance from Stanley Bram, the evidence fails to support a finding that such assistance related to the patent at issue. Respondents contest the assertion that it was necessary to invoke Bram "as a guide to anything; the prior art clearly point[ed] the way." Respondents' Br. at 24. Complainant's witness on this issue, Dr. Jean

Irunberry, failed to establish in his testimony that Bram's technical assistance under the 1976 agreement or under the 1977 secrecy agreement concerned issues relevant to claims 5, 8 and 9 of the Bram patent. FF 220a, 221. Such contracts under the various agreements may have produced structural or electronic refinements to the Numelec or Laboratorium Berthold devices unrelated to the Bram patent, yet central in meeting the requirements of the biomedical field. As noted in Vandenberg v. Dairy Equipment Co., 740 F.2d 1560, 1567, 224 U.S.P.Q. 195 (1984), such refinements are not appropriately characterized as objective evidence of nonobviousness. Cf. Medtronic Inc. v. Daig Corp., 611 F.Supp. 1498, 1531, 227 U.S.P.Q. 509 (D.C. Minn. 1985), aff'd Medtronic, Inc. v. Daig, 789 F.2d 903, 229 U.S.P.Q. 664 (1986); cert. denied Daig Corp v. Medtronic, Inc., 107 S. Ct. 402 (1986) (establishing that commercial success suggested nonobviousness of the disputed patent).

Complainant's reliance upon Panduit Corp. v. Dennison Manufacturing Co., 774 F.2d 1082, 1099-1110, 227 U.S.P.Q. 337, 348-349 (Fed. Cir. 1985) cert. granted and vacated, 106 S. Ct. 1578, 229 U.S.P.Q. 478 (1986), on remand, 810 F.2d 1561, 1 U.S.P.Q. 2d 1593 (7th Cir. 1987), is highly misplaced because the development of the Bioscan, Berthold, and Numelec devices does not establish that the claimed invention is nonobvious. The evidence fails to support complainant's assertion that the Numelec, Berthold, Isomess/Stratec or Aloka devices resulted from Bram's claimed invention. The evidence does not show that the development of current commercial chromatogram analyzers derived from Bram. Despite Bram's association with Numelec, the Numelec device was not a commercial success. FF 222.

d. Long felt need.

Nonobviousness of an invention is also revealed by analyzing it in terms of whether it satisfied a long felt need in the field. With respect to Bram's patented chromatogram analyzer, complainant has failed to establish that Bram's device filled such a need in the field. Complainant relies upon U.S. Philips Corp. v. National Micronetics Inc., 550 F.2d 716, 722 (2d Cir. 1977) cert. denied, 434 U.S. 859, 98 S. Ct. 183 (1977), to support its argument that Bram's invention filled a gap in the chromatogram analyzer market. However, in that case the evidence established that experts in the industry had searched unsuccessfully for nearly a decade for a process to reproduce minute gap dimensions which were later successfully invented by the owner of the patent in dispute. The subject patent "produced a result unobtainable with the prior processes." Id. at 723. Moreover, the court referred to the huge gap between the prior art and the subject patent as the "difference between success and failure." Id.

The evidence at bar does not warrant a finding that Bram's invention satisfied a deficiency in the prior art. Rothberg, Tr. 461-62; Polic Dep., CX 133 at 87. Contrary to the facts established in W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1541, 1545 (Fed. Cir. 1983) cert. denied, 469 U.S. 851, 105 S. Ct. 172 (1984), imaging chromatogram analyzers made contemporaneously and independently of the Bram patent did not satisfy a long felt need for the device in the industry. The introduction into the market of chromatogram analyzers today satisfies only a need in the biomedical field for commercialization of the product, not a long felt need in the market for Bram's claimed improvement over the prior art. See Pentec, 776 F.2d at 316. Therefore, the objective evidence of the art prior to Bram's invention fails to support complainant's contention that its patent is nonobvious.

e. Failure of others.

The Bram patent claims are further undermined by complainant's weak arguments as to failure of others to commercialize imaging chromatogram analyzers. Asserting that such failure establishes that counsel's construction of Bram's patent was nonobvious, complainant suggests that the failure to commercialize this technology prior to the late 1970's provides objective evidence of Bram's nonobviousness. However, the court in Orthopedic Equipment Co. v. United States, 702 F.2d 1005, 1013 (Fed. Cir. 1983), clearly differentiated between economic factors and technological incompatibility, finding that only the latter served as evidence of nonobviousness.

Prohibitive costs contributed to the lag in the technological development of a commercially saleable model of an imaging windowless gas flow counter. Polic, Tr. 564-66; Shulman, Tr. 116. Significant recent advances in biomedical technology have largely been due to the commercial introduction of personal computers with vast memory storage capabilities into the consumer market during the past five years. Such advances have spurred the commercial marketing of position-sensitive proportional counters. Polic, Tr. 667. The Borkowski and Kopp position sensitive proportional counters were not commercialized in the earlier 1970's because of the expensive electronics required. Shulman Dep., RX 52 at 242-243; Polic Dep., CX 133 at 34-38; Shulman, Tr. 116, 220; Polic, Tr. 518, 567. As in Orthopedic Equipment, 702 F.2d at 1013, the failure to commercialize immediately does not alone support a finding of nonobviousness.

Contrary to complainant's assertion, the prior art does not evidence a "failure of others" to address problems concerning the detection of radiation from low-energy chromatogram samples of certain elements. Perkin-Elmer, 732 F.2d at 894. Since the problem addressed by Bram had already been fully resolved in the prior art, the claimed invention as construed by counsel is clearly obvious. Rothberg, Tr. 447-49. As enunciated by the court in In re Farrenkopf, 713 F.2d 714, 718 (Fed. Cir. 1983), strong evidence of obviousness in the prior art invalidates patent claims. Moreover, in 1975 Dr. Shulman succeeded in inventing an imaging detector system without any prior knowledge of Bram or chromatography. Shulman, Tr. 95-100, 296.

Thus, the objective criteria or secondary considerations do not clearly show that claim 5 of the Bram patent was nonobvious.

6. Conclusion as to Obviousness

If claims 5, 8 and 9 of the Bram patent were construed to define an imaging radiation detector of the windowless gas flow type or of the gas tight completely enclosed chamber type it would be obvious. As acknowledged in the Bram patent, and as shown abundantly by other evidence, such devices were a clearly established part of the prior art. Consideration of the secondary factors does not alter this conclusion.

What is new and nonobvious about the Bram patent is the detection of low energy radiation in a chamber pressurized beyond atmospheric levels, and as so interpreted claims 5, 8 and 9 are nonobvious. However, none of the secondary considerations mandates this conclusion of nonobviousness. For example, there is no evidence of the commercial success of pressurized detection chamber devices.

C. Enablement

Under 35 U.S.C. § 112 the specification of a patent must contain a description of the invention and of the manner and process of making and using it. It must be written in terms which are sufficiently "full, clear, concise, and exact," to enable any person skilled in the relevant art to make and use the invention. 35 U.S.C. § 112. It need not be enabling to an unskilled lay person and may assume that which is common and well known to persons skilled in the relevant art. 2 Chisum, Patent, § 7.03[2] at 7-18. Thus, a specification will be enabling provided it does not require an undue amount of experimentation. Cross v. Iizuka, 753 F.2d 1040 (Fed. Cir. 1985). As a patent is presumed to be valid, the party attempting to invalidate a patent for lack of enablement bears the burden of proving so by clear and convincing evidence. Ralston Purina Co. v. Far-Mar-Co., Inc., 227 U.S.P.Q. 177 (Fed. Cir. 1985).

Respondents assert on several grounds that the Bram patent does not enable one skilled in the art to make and use the claimed inventions of claims 5 and 9 without undue experimentation. Respondent's Prehearing Statement at 16. The Commission Investigative Staff agrees with the respondent with respect to claim 9 but asserts that claim 5 meets the enablement requirement.

With respect to claim 5, respondents contend that the counting chamber as described in the Bram patent's specification is inoperative because the placement of the anode and cathode would result in charge build-up on the walls of the chamber. Respondents further argue that the specification does not adequately describe how to overcome this problem, thus requiring one seeking to replicate the device to undertake undue experimentation.

Expert testimony indicated the principal embodiments as described in the specification are inoperative because of charge build up. Rothberg, Tr. 400; Shulman, Tr. 206-07, 211; Polic, Tr. 503-04. However, expert testimony was also adduced indicating that the potential for a problem of positive charge build-up existed in all proportional counters and that one building the Bram device would know to coat the walls of the chamber with a conductive material. Shulmam, Tr. 384. Respondents have failed to establish by clear and convincing evidence that the knowledge generally available in the relevant art would not have allowed one of ordinary skill in that art to make the disclosed invention. .

Respondents also contend that claim 5 is invalid for lack of enablement for failing to describe the voltage at which the device is to be operated. However, the specification of the Bram patent states that it is to be operated at a voltage of 1300 volts. FF 75; CX 4, col. 5, lines 45-46. Further, the specification repeatedly states that the Bram patent is for a proportional counter. It is of general knowledge in the art of radiation detection that proportional counters operate within the range of 1200 to 1700 volts. FF 43.

Respondents' final grounds for claim 5 not being enabled are based on alleged imprecision concerning the dimensions of the device, the distance of the object being sampled from the detecting anode wire, the location of the anode, and whether the device counts beta particles or the secondary electrons caused by ionization. With respect to each of these grounds, there was expert testimony that one of ordinary skill in the art would have the general knowledge necessary to make the device without these details. Shulman, Tr. 163-67.

Claim 9 combines the apparatus of claim 5 with "a means connected to said counting means for preventing the counting of those particles not travelling at an angle substantially perpendicular to said object." CX 4, col. 10, lines 17-19. This language suggests that the claimed invention is intended to count the individual beta particles that are emitted from the object rather than the secondary electrons freed through ionization by the beta particles. CX 4, col. 2. Expert testimony shows that electronics with the sensitivity to detect a single particle do not exist today nor did they in 1974. Rothberg, Tr. 407, 485; Rothberg Dep., CX 134 at 118; Polic, Tr. 542. Construing claim 9 in light of the concepts of gas multiplication and proportional counting, it is the secondary electrons which are the "particles" counted.

Beta particles that travel perpendicularly from the sample toward the anode have a shorter path through the ionizable gas than do those travelling at an angle from the sample. As such, those travelling perpendicularly do not free as many electrons through ionization. Shulman, Tr. 252. A device intended to count only the particles travelling perpendicularly from the sample as required by claim 9 would record only the small pulses produced by the lesser number of freed electrons. Large pulses are the result of angular particles and therefore should be rejected. Rothberg, Tr. 412.

However, the specification of the Bram patent states that the smaller pulses are to be rejected in favor of the larger ones. FF 257. Therefore, Bram's system of electronic collimation by pulse-height discrimination counts only those angular particles which the system should reject. Complainant's expert witness suggested that Bram is looking at negative pulses and is blocking pulses that are below a minimum threshold in the negative direction.

Shulman Dep., RX 52 at 92. The witness admitted, however, that there was nothing in the specification indicating that Bram was looking at negative pulses. Id. at 92-93; FF 260. Further, there is expert testimony that one skilled in the art would interpret the Bram specification to mean that the smaller pulses are to be rejected. Rothberg, Tr. 427; Polic, Tr. 544. One skilled in the art would not know to make the device so that the larger pulses are rejected instead. Id. He would be unable to make and use the invention claimed in claim 9 without performing an undue amount of experimentation. Thus, claim 9 is invalid for lack of enablement.

D. Conclusion as to Validity

Claims 5 and 8 of the Bram patent are valid and nonobvious as interpreted. Claim 9 is invalid for lack of enablement.

IV. PATENT INFRINGEMENT

The '057 patent relates to a method and apparatus to determine "the spatial distribution of radioactivity within an object emitting radioactive particles, especially those of low energy." CX 4, Abstract. An object of the patent was the avoidance of scanning the surface of a radioactive object on a point by point basis "with a particle detector covered by a narrow slit to measure the radiation intensity at each point." Id., at Col. 1, lines 30-47. The inventor sought to modify various prior art devices, which were used to detect high energy radiation, in detecting low energy radiation for use in biological and chemical analysis. Id., at col. 1, lines 53 to end; col. 2, lines 1-51. The gas-filled chamber of the high energy particle detector of the '377 patent had thick windows of steel or beryllium, and the mere substitution of thin windows would not be satisfactory for detecting low energy isotopes such as tritium or carbon 14. Ibid. The inventor sought not merely to measure low energy radiation, for this had been done, but to increase the "efficiency" (defined as "the ratio of particles detected to particles emitted") and the "spatial resolution," i. e., the location of the radiation along the surface of the object to be measured. The inventor noted that "pressurization" would increase efficiency, but use of a "thick window will result in a corresponding loss of resolution." CX 4, col. 2. Placing "a radioactive object inside the chamber eliminates the need for a window" and thus a window would no longer be interposed "between the object and the wire". Id., at Col. 2, lines 5-7; Col. 6, lines 27-29. The object of the invention is realized by placing the radioactive object within the chamber which "is then sealed with a strong material to enable pressurization of the chamber beyond atmospheric pressure." Id., at Col. 4, lines 36-40.

Complainant has the burden of proving infringement by a preponderance of the evidence. Hughes Aircraft v. United States, 717 F.2d 1351, 1361 (Fed. Cir. 1983). A determination of infringement begins with an analysis of the scope of the claims. Raytheon Co. v. Roper Corp., 724 F.2d 951 (Fed. Cir. 1983). It is well settled that the claimed invention is not limited to the specific embodiments disclosed in the patent specification and drawings. Id., at 957; Environmental Designs, Ltd. v. Union Oil Co. of California, 713 F.2d 693 (Fed. Cir. 1983). However, the claim language is construed in light of the specification. United States v. Adams, 383 U.S. 39, 49 (1966). "[A]lthough the specifications are merely an example of what is claimed, they are useful interpretative aids." Eastern Electric, Inc. v. Seeburg Corp., 310 F. Supp 1126, 1132 (S.D.N.Y. 1969).

Thus, infringement is not determined by comparing the infringing product with the preferred embodiment described in the patent specification or with a commercialized embodiment of the patentee, but rather with the properly construed claims of the patent. SRI International v. Matsushita Electric Corp. of America, 775 F.2d 1107, 1121 (Fed. Cir. 1985). Inventors cannot possibly anticipate all conceivable structures that may come within the scope of the claimed invention. Id.

If an accused structure falls clearly within the language of the patent claim, then literal infringement is established. Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 604 (1950); Envirotech Corp. v. Al George, Inc., 730 F.2d 753 (Fed. Cir. 1984). If the accused device does not literally infringe, infringement may be established if the accused device performs substantially the same function in substantially the same way to achieve substantially the same result as the claimed invention. Graver Tank, 339 U.S. at 608; Envirotech Corp., 730 F.2d at 760, 761.

A. Literal Infringemnt

Complainant contends that respondents' products infringe claims 5, 8 and 9 of the '057 patent. Claims 8 and 9 depend upon 5 and contain further limitations.

Claim 5 of the '057 patent provides as follows:

1. "...a completely enclosed chamber containing an ionizable gas..."

2. "...an elongated conductor extending longitudinally of and fixedly secured within said chamber..."

3. "...at least a portion of one wall of [the] chamber being removable...".

4. "...a support attached inside [the] chamber...to mount [the sample]...in close proximity and substantially parallel to the anode wire..."

5. "...means for counting [the quantity of radioactivity] at a plurality of locations [along the length of the anode wire]..."

CX 4.

There is no substantial factual dispute concerning the structure of the accused devices, or the patent documents. The primary issue of contention between the parties is the construction of the claims. The complainant asserts that the phrases in claim 5 of the '057 patent, a detector having "a completely enclosed chamber," and "a support . . . inside said chamber walls" and other similar language read on respondents' devices, although the detectors in the latter devices are not sealed for operation at beyond atmospheric pressure, as are the detector embodiments in the '057 patent.

A patentee may be his own lexicographer. The plain meaning of claim language is presumed unless the patentee, in the claim specification and other patent documents, disclosed an intent to use the term in a special way. Claims are ordinarily construed as they would be by those of ordinary skill in the art. Fromson v. Advance Offset Plate, Inc., 219 U.S.P.Q. 1137, 1142 (Fed. Cir. 1985). Thus, appropriate information must be examined to determine what is meant by use of the terms "a completely enclosed chamber" and "inside" the chamber, or "within" the chamber.

The specification describes a low energy radiation detection device which is pressurized beyond atmospheric pressure, and which is a modification of the Borkowski and Kopp '377 patent and the position sensitive detector developed by Kaplan and others. CX 4, cols. 2-3; FF 75a, 79. In the '377 device a window was placed between the anode and the object to be analyzed. CX 4, col. 2, lines 16-24. In the Bram device the window is eliminated because the radioactive object is placed "inside the detector." Id., at col. 3, lines 5-8. Thus, only the gas is between the object and the anode. The Kaplan multiwire pressurized chamber is utilized in Bram (Figs. 4-7, and face page). However, the electronics of Kaplan are modified because for one dimensional autoradiograms "it is [a] very costly device." Id., at col. 3, lines 49-52. For two and three dimensional spatial resolution for low energy emitters the electronics of Kaplan are further simplified. Id., at cols. 3-4, lines 52 to end and lines 1-42.

Two embodiments are described in the specification, one illustrated in Figure 6, "which is the apparatus of the present invention," and the other is illustrated in Fig. 7 which is an embodiment "wherein two sets of conductors are utilized, one below and one above the radioactive object." Cols. 4-5, lines 63 to end and carryover to col. 5, lines 1-2. There are also two variations of the detector chamber, in which the anode and sample support have different placements. CX 4, figs. 6, 7. In addition, mention is made of the possibility of using a thin window with the sample outside the window if pressurization is inconvenient. Id., at col. 8, lines 12 - 32. However, except for uses where the pressurized chamber is inconvenient, the Bram specification consistently describes a chamber which is pressurized beyond atmospheric pressure. Polic Tr. 497-500, 586-87. What Bram had in mind was that "high pressure will improve resolution." Rothberg, Tr. 404-05, 408-09; CX 4 col. 6, lines 36-45; FF 268.

Complainants contend that the claim language "completely enclosed" chamber reaches respondents' devices although they are not capable of being pressurized beyond atmospheric pressure. Complainant contends that respondents' devices contain completely enclosed detector chambers because the table which supports the object to be analyzed mates with the detector head so that the ionizing gas extends beyond the bottom level of the detector chamber and suffuses the object. Complainant's Post Hearing Br. at 42. None of the commercial products, including the complainant's products, have a sealed chamber. FF 269-73. They are windowless flow counters. Polic, Tr. 506. The difference between the current commercial products of all parties and commercial versions of radioactive detectors available in the early 1970's is that the current products can analyze all the radioactivity in one track at one time, and can go from track to track, whereas the earlier models could analyze radioactivity only a point at a time. Polic, Tr. 516-18; CX 4, col. 1, lines 30-47.

Operation in a sealed, closed chamber under pressurization is different than the operation of windowless flow counters. Polic, Tr. 506-07. In the windowless detector the gas is flowing from entrance to exit. Rothberg, Tr. 422. In the windowless flow counter the sensitizing gas volume and electric fields cover the sample by moving down over it through the slit in the detector wall. Polic, Tr. 557. In the pressurized chamber there is no gas flow. The gas enters and it is pressurized. Rothberg, Tr. 422-23. However, both types detect radioactivity the same way; i.e., covering the radioactive sample with ionizable gas together with electronic detection. Polic, Tr. 576-77. Complainant argues that it is only necessary that the sample be in the sensitive gas volume at the time of measurement, and during measurement the sample is completely enclosed. Therefore, according to complainant, claim 5 reads on respondents' products.

This construction of the claim language, however, would result in the invalidity of the patent, for in that case claim 5 would read on windowless proportional flow counters (category two of the prior art) and gas tight radioactive detecting cambers, which are completely enclosed except for an inflow gas port (category one of the prior art) in combination with position sensing electronics (category three of the prior art). Claims however must be construed in a manner which will preserve the validity of the patent. <u>ACS Hospital Systems, Inc. v. Montefiore Hospital</u>, 221 U.S.P.Q. 929 (Fed. Cir. 1984).

To preserve the validity of the patent claims, a "completely enclosed" chamber, consistent with the specifications, must be pressurized for operation beyond atmospheric pressure. Complainant contends that claim 5 cannot be interpreted to require a pressurized chamber, because dependent claims 6 and 7 contain the limitation of pressure "significantly higher than atmospheric pressure." (Emphasis added.) It is true that the limitations of a dependent claim cannot be read into an independent claim. Kalman v. Kimberly-Clark Corp., 218 U.S.P.Q. 781 (Fed. Cir. 1983). However, the inventor has made a distinction between "beyond atmospheric pressure" and "significantly beyond atmospheric pressure." At one point in the specification it is provided that window 30 should be "strong enough to withstand pressure significantly higher than atmospheric pressure," (CX 4, col. 7, lines 13-15) whereas all other references to pressurization of the chamber in the specification refer only to "beyond atmospheric pressure." (Emphasis added.) For example window 30' is not strong enough for significantly higher than atmospheric pressure. It is "considerably thinner" than window 30, and requires a "supporting grid" or "retaining bar" for pressurized operation. Id., at col. 8, lines 24-33. Consequently, variations of the Bram device can operate both at beyond atmospheric pressure, and significantly beyond atmospheric pressure, for still further improved resolution.

The two disclosed embodiments involve a sealed chamber. They are unlike the chamber of the windowless flow counter, in which the primary exit for the gas is a slit in the detector chamber, outside of which sits the object to be analyzed, but like the earlier sealed chamber detectors, such as is shown in the Borkowski and Fairstein '925 patent. FF 90. The chamber in each of the embodiments which illustrates what is patented is sealed for operation at beyond atmospheric pressure levels. CX 4, figs. 2a and 2b. In this way the inventor believed not only that spatial resolution and counting efficiency would be improved, but that two and three dimensional position sensivity could be achieved. FF 75a; CX 4, col. 4, lines 15-18. Windowless flow counters cannot be operated at beyond atmospheric pressure.

Complainant argues that the basic inventive feature of the Bram patent is a position sensitive radiation detector. However, this is not in any respect reflected in the drawings or body of the Bram patent. On the contrary, an examination of the drawings and the specification supports the view that the inventor considered the position sensitive radiation detector part of the prior art, and that his invention is a pressurized device giving improved spatial resolution and also in which two and three dimensional resolution could be achieved. Figure 1 of the drawings in Bram is labeled as the "Prior Art." It shows a radiation detector including the position sensitive electronics. The textual description also provides that it is "a prior art circuit for determining the spatial distribution of radioactivity in an object." CX 4, col. 4, lines 49-51. See also, claim 1, element a., in which the inventor assumes a person of skill in the art knows what a "position sensitive radioactivity detector" is. Id., at col. 9, lines 19-20. Thus, the inventor assumed that a position sensitive radiation detector was part of the prior art, as indeed it was.

It appears rather that the inventor primarily was modifying the cited Kaplan device (see above fourth category of prior art) for use in improving the detection of spatial distribution of radioactivity within an object. Id., at col. 3, lines 59-68; col. 4, lines 1-7; Polic, Tr. 546-47. Kaplan discusses multiwire proportional counters and two and three dimensional position resolution in radiation detection by use of pressurized chambers and various electronic circuits generally described in Bram. Ibid. Figures 4 through 7 depict multiwire radioactive detectors similar to those used by Kaplan, as does the drawing on the face page of the patent. Figure 3 is a drawing of a sample tray which could be used in a multiwire detector. Figure 2, the only remaining drawing, is of the chamber without the wires or gas ports shown. Kaplan teaches that improved resolution can be obtained by "operating the chamber at higher-than-atmospheric pressure." CX 1, at 404 of the Kaplan article. The Kaplan article was cited as a reference in the original application, and was listed as one of the references in the reexamination proceeding. Improved two- and three-dimensional spatial resolution in detecting low energy particles with greater efficiency, and detection of gamma (high energy) radioactivity with improved efficiency and resolution were listed as objects of the Bram patent along with the general objective of improvement of spatial resolution and quick measurement.

Further, the record of the prosecution and reexamination of the Bram patent does not reflect that the patent examiner believed that the large body of prior art related to windowless proportional counters was relevant to Bram. Included in this body of prior art is U.S. Patent No. 3,603,831 awarded to Hermann Kimmel. The Kimmel patent is classified under subcategory 83.6 of category 250. FF 113a. The list of those classes and subclasses of patents which were searched by the examiner prior to granting the Bram patent indicates that this subcategory was not searched by him. FF 175a. Had the examiner thought the Bram device would cover windowless flow counters, he would have searched subcategory 83.6 and referenced work from this category of art. The examiner apparently did not believe that Bram's sealed, pressurized chamber device, related to windowless flow counters.

There is no windowless mode described in the specification, i.e, the chamber is not designed to operate with a slit in the wall or a window removed (although there is mention in the specification of placing a sample outside a thin supported window). CX 4, col. 8, lines 18-23. Operation in the windowless mode would not be possible in a device which operates at levels beyond atmospheric pressure, because the flowing gas is sufficient only to drive away the air so that the top part of the sample is in the sensitive gas volume, and windowless flow counters are otherwise open to the atmosphere.

Complainant, or its predecessor has built a pressurized device (CPX 3), and originally sought a grant to construct this device. In 1980 it was sold to the National Institutes of Health. FF 217b. CPX 3 is considerably different from the devices currently sold by the complainant and respondents. It is designed so that the outer walls can withstand pressurization beyond atmospheric pressure. The top plate is held down by numerous screws. There is a pressure relief valve, and the device is capable of detecting radiation from more than one channel at a time. FF 211b. It contains a sealed, completely enclosed chamber, capable of pressurization, but apparently its inconvenience of operation resulted in discontinuance of production, and change to the current type of product. FF 217c.

The claims must be construed as they would be by a person of ordinary skill in the art. Standard Oil Co. v. American Cyaninid Co., 227 U.S.P.Q. 293 (Fed. Cir. 1985). A person of skill in the art is presumed to be aware of all the prior art. Id. Thus, a person of skill in the art, in light of the specifications of the '057 patent, and the prior evolution of radioactive detector devices, would understand the term "completely enclosed" chamber as a detector chamber which is sealed for pressurization of the gas at beyond atmospheric levels, and that this term excludes windowless flow counters, because such devices cannot be pressurized beyond atmospheric pressure. Merely indicating that there are undisclosed variations or embodiments as a preface to the claims would not expand the term "completely enclosed" chamber to include devices not designed to operate at beyond atmospheric pressure, such as windowless flow counters. These undisclosed embodiments or variations could include further variations in the type of windows, consistent with pressurized operation, and variations in the placement of the anode, the sample support, and the cathode in the pressurized chamber.

The respondents' devices do not contain sealed chambers which can be pressurized at beyond atmospheric pressure. They are essentially modern versions of windowless flow counters, with position sensing electronics. Complainant's devices are of the same character. FF 263-73; 279-96. As construed herein claims 5, 8 and 9 of the patent do not read on the respondents' devices, since they are not capable of operation at beyond atmospheric pressure. Therefore, respondents' products do not literally infringe claims 5, 8 and 9 of the '057 patent.

B. The Doctrine of Equivalents

A patentee is not bound by the literal language of the claims and specification. The doctrine of equivalents may expand the scope of the patent because "to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing." A finding of equivalence, namely, that a device performs substantially the same function, in substantially the same way to obtain the same result, is a determination of fact. Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 609 (1950).

A pioneer invention performing a function never before performed is entitled to liberal application of the doctrine of equivalents. Sealed Air Corp. v. U.S. International Trade Commission, 209 U.S.P.Q. 469, 477 (C.C.P.A. 1981). An invention representing only a modest advance over the prior art is given a more restricted (narrower range) application of the doctrine. When a patentee claims an improvement over an earlier invention, other parties are entitled to practice variations of that prior invention, so long as they are not the same as, or an equivalent of, the improvement claimed by the patentee. Thomas & Betts Corp. v. Litton Systems, Inc., 720 F.2d 1572 (Fed. Cir. 1983).

Application of the doctrine of equivalents would not require that the respondents' products be disclosed in the patent. Properly construed claim language must be given the appropriate range of equivalents. The Bram patent is a slight improvement over the devices described in the Kaplan article, and in the '377 patent. It is thus entitled to a narrow range of equivalents.

Complainant argues that under the doctrine of equivalents claims 5, 8, and 9 of Bram read on the proportional flow counters of the respondents. The respondents' devices are viewed by complainant as containing a completely enclosed chamber, in that the table which supports the sample is considered the removable wall, and when the detector head, the sample, and the sample support table are moved close together, under the doctrine of equivalents, the devices would include all the elements of claim 5 of Bram. The clear response to this view is that the respondents are entitled to practice the prior art.

The doctrine of equivalents cannot be used to expand claim language to encompass what was well known in the prior art. It is acknowledged in the Bram patent that position sensitive radiation detection is part of the prior art, whether the detectors are windowless flow counters or completely enclosed chambers as exemplified by the '925 Borkowski patent.

The chamber referred to in the claims of the Bram patent is one that is pressurized for operation beyond atmospheric pressure. It is an improvement on the devices described above for improved spatial resolution in the measurement of low energy radioactive emitters. Variations in multiwire and pressurized operation for improved spatial resolution of low energy emitters could be reached by the doctrine of equivalents, but prior art position sensing windowless flow counters, which are not operated at beyond atmospheric levels, could not be covered by the doctrine of equivalents.

Therefore, the products of the respondents do not infringe claims 5, 8 and 9 of the '057 patent, either literally or under the doctrine of equivalents.

V. IMPORTATION AND SALE

To invoke the subject matter jurisdiction of the Commission and to support
a finding that a violation of Section 337 exists, complainants must establish
that the accused product has been imported and/or sold in the United States.
Both respondents in this investigation have imported and sold in the United
States chromatogram analyzers alleged to infringe the '057 patent. In
C* calendar 1986, IN/US sold of its Radioactivity Intelligent Thin-Layer
Analyzer (RITA) devices in the United States for a total of at least
C $. FF 362. During 1985/1986 Radiomatic sold of its Model RS TLC
scanner imaging chromatogram analyzers in the United States for a total of
C $. FF 372.

Therefore, chromatogram analyzers alleged to infringe the '057 patent have been imported and sold in the United States.

* = Confidential

VI. DOMESTIC INDUSTRY

In patent, trademark, or copyright cases, the domestic industry is defined as the domestic operations of the complainant devoted to the intellectual property right at issue. See Certain Cloisonne Jewelry, Inv. No. 337-TA-195, at 58 (1986); Certain Foam Ear Plugs, Inv. No. 337-TA-184 (1985); Certain Drill Point Screws, Inv. No. 337-TA-116, at 11-12 (1982). The Commission has customarily defined the domestic industry in patent-based investigations as the domestic operations of the patent owner and its licensees devoted to the exploitation of the patent. Schaper Manufacturing Co. v. U.S. International Trade Commission, 717 F.2d 1368, 1372 (Fed. Cir. 1983); Certain Methods for Extruding Plastic Tubing, Inv. No. 337-TA-110, 218 U.S.P.Q. 348 (1982); Certain Slide Fastener Stringers and Machines and Components Thereof, Inv. No. 337-TA-85, 216 U.S.P.Q. 907 (1981); see H.R. Rep. No. 93-571, 93 Cong., 1st Sess. 78 (1973). The domestic industry is not limited to manufacturing per se but may encompass distribution, research and development, and sales. Certain Personal Computers, Inv. No. 337-TA-140, 224 U.S.P.Q. 270 (1984). The Commission does not adhere to any rigid formula in determining the scope of the domestic industry, as it is not precisely defined in the statute, but will examine each case in light of the realities of the marketplace. Slide Fastener Stringers; Certain Apparatus for the Continuous Production of Copper Rod, Inv. No. 337-TA-52, 206 U.S.P.Q. 138 (1979); see Certain Double-Sided Floppy Disk Drives, Initial Determination, Inv. No. 337-TA-215, at 49-56 (1985).

The products of the complainant do not contain a detector chamber which is pressurized beyond atmospheric pressure. FF 273. The original commercial product was of this character. CPX 3. However, only one was sold in 1980, and because it was unsaleable complainant switched to the current product which is a non-pressurized gas flow counter. FF 217c. Consequently, since claim 5 requires a product which contains a pressurized chamber, and since the complainant's products do not contain this element of the claim, complainant is not exploiting the patent rights of the Bram patent, and for this reason there is no domestic industry.

If the claims are construed not to require pressurization then there is a domestic industry. Since 1980, Bioscan has been the sole domestic manufacturer of imaging chromatogram analyzers capable of sensing ^{3}H. FF 328. Bioscan currently offers three models of imaging chromatogram analyzers, the System 200, System 400, and System 500. FF 332. The basic

C Bioscan system includes

C

C

C

C . FF 333.

C

C

C

C

FF 334.

Although Bioscan's licensee, Berthold, sold chromatogram analyzers in the United States, Complainant offered no proof that Berthold is a U.S. producer. FF 344. Therefore, Berthold will not be included in the domestic industry in this investigation.

VII. EFFICIENT AND ECONOMIC OPERATION

In order to prevail under Section 337, a complainant must establish that the domestic industry is efficiently and economically operated. The guidelines set forth by the Commission to assess whether a domestic industry is efficiently and economically operated include: (1) use of modern equipment and manufacturing facilities; (2) investment in research and development; (3) profitability; (4) substantial expenditures in advertising, promotion, and development of consumer goodwill; (5) effective quality control programs; and (6) incentive compensation and fringe benefit programs for employees. See e.g., Certain Methods for Extruding Plastic Tubing, Inv. No. 337-TA-110, 218 U.S.P.Q. 348 (1982); Certain Coin Operated Audio Visual Games and Components Thereof, Inv. No. 337-TA-105, 216 U.S.P.Q. 1106 (1982); Certain Slide Fastener Stringers and Machines and Components Thereof, Inv. No. 337-TA-85, 216 U.S.P.Q. 907 (1981).

Bioscan meets the standards required for efficient and economic
C operation. Since 1980, Bioscan has spent substantial sums on
C . FF 345. Bioscan utilizes
C
C . FF 348-49, 353-54. Bioscan's production process
C includes
C
C
C . FF 351-52.
C . FF 352.

VIII. SUBSTANTIAL INJURY

As a final element in a Section 337 investigation, complainant must show that respondents' unfair methods of competition and unfair acts have the effect or tendency to destroy or substantially injure the domestic industry. 19 U.S.C. § 1337(a). Injury requires proof separate and independent from evidence of an unfair act. Complainants must establish a causal relationship between respondents' unfair acts and the injury suffered by the domestic industry. Certain Spring Assemblies and Components Thereof and Methods of Their Manufacture, Inv. 337-TA-88, 216 U.S.P.Q. 225, 243 (1981).

Section 337(a) states in part that it is unlawful for an owner, importer, consignee, or agent of either, to participate in (1) unfair methods of competition and unfair acts, (2) in the importation of articles into the United States, or in their sale, (3) the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States, or to prevent the establishment of such an industry. 19 U.S.C. § 1337(a). All elements of § 337 must be established if complainant is to prevail. However, the existence of each element is not sufficient evidence of a violation of § 337 where one element is not related to another. See generally, Certain Centrifugal Trash Pumps, Inv. 337-TA-43, 205 U.S.P.Q. 114, 117 (1979). The unfair methods of competition or unfair acts must be in the importation or sale of the subject articles such that the combination of these two elements destroys or substantially injures a domestic industry.

Several factors are relevant to a determination of substantial injury to a domestic industry, including, but not limited to: (1) declining sales; (2) volume of imports and capacity to increase imports; (3) loss of market share; (4) lost customers; (5) decreased employment; (6) decreased production and profitability; (7) underselling; and (8) excess domestic capacity. See e.g., Certain Vertical Milling Machines and Parts, Attachments, and Accessories Thereto, Inv. 337-TA-133; 223 U.S.P.Q. 332, 348, (1984); Certain Drill Point Screws for Drywall Construction, Inv. 337-TA-115 (1983); Spring Assemblies, 216 U.S.P.Q. at 242-45; Certain Roller Units, Inv. 337-TA-44, 208 U.S.P.Q. 141, 144 (1979). Although the Commission considers a variety of factors in deciding whether the domestic industry has been injured, the determination of injury is dependant upon the particular facts of each investigation. Drill Point Screws, Rd at 144.

Until the introduction of the Radiogram RS TLC chromatogram in April 1985, Bioscan and its licensee Berthold were the only companies marketing imaging chromatogram analyzers in the United States. FF 344. This assumes that the definition of chromatogram analyzers includes only those analyzers that can measure soft beta radioactivity from ^{3}H, ^{14}C, or ^{32}P, in which case the AMBIS Beta Scanning System is not an imaging chromatogram analyzer. FF 355. In fact, most of the potential customers for the imaging chromatogram analyzers sold by Bioscan, IN/US, and Radiomatic desire to measure soft beta radioactivity from ^{3}H, ^{14}C, or ^{32}P. FF 356. Today, the United States market for imaging chromatogram analyzers is divided among Bioscan, Berthold, and respondents IN/US and Radiomatic. FF 357. Bioscan, with its imaging chromatogram analyzers, Radiomatic, with its Model RS TLC scanner imaging chromatogram analyzer, and IN/US with the RITA imaging chromatogram analyzer, have all directly competed and continue to compete for sales to some of the same potential customers in the United States. FF 358-59.

From its fiscal year 1983 (November 1, 1982 to October 31, 1983) to
C fiscal year 1986, Bioscan's chromatogram analyzer sales
C . FF 337-40. Bioscan's employment
C . FF 353.

A. IN/US

Respondent IN/US offers its RITA model chromatogram analyzer throughout the United States through sales representatives. FF 361. In 1986, IN/US sold
C , in the United States. FF 362.
C Bioscan had also made sales efforts for of these customers, including
C price quotations and demonstrations. FF 365.
C . FF 365. Bioscan's
C prices range from $ for its three analyzer models.
C FF 329-32. IN/US's prices for its sales ranged from $ for
its 1986 sales. FF 362. As evidenced by correspondence between IN/US and
C ISOMESS and the sales representatives of IN/US,
C
C . FF 366. In 1986, IN/US had percent of the U.S.
chromatogram analyzer market. FF 340, 343, 362, 372. The actual percentage may be higher because Bioscan's and Berthold's sales used to calculate the U.S. market represented worldwide sales.

B. Radiomatic

Radiomatic offers the Model RS TLC scanner imaging chromatogram analyzer for sale throughout the United States. FF 368. From September 1985 to
C December 1986, Radiomatic sold Model RS TLC chromatogram analyzers in the
C United States, valued at $. FF 372. Some of these imaging chromatogram analyzers were sold with various computers or without any
C computer. FF 372.

C . FF 373. As evidenced by its responses to various discovery inquiries during this investigation,
C
C . FF 374. In 1986, Radiomatic had
C percent of the U.S. chromatogram market. FF 340, 343, 362, 372. The actual percentage may be higher because Bioscan's and Berthold's sales used to calculate the U.S. market represented worldwide sales.

Because respondents have captured significant market share from complainant Bioscan, and because of the confirmed lost sales, I determine that Bioscan has been substantially injured by reason of chromatogram analyzer imports by IN/US and Radiomatic.

IX. TENDENCY TO SUBSTANTIALLY INJURE

When an assessment of the market in the presence of the accused imported product demonstrates relevant conditions or circumstances from which probable future injury can be inferred, a tendency to substantially injure the domestic industry has been shown. Certain Combination Locks, Inv. No. 337-TA-45, Recommended Determination at 24 (1979). Relevant conditions or circumstances may include foreign cost advantage and production capacity, ability of the imported product to undersell complainant's product, and the potential and intention to penetrate the United States market. Certain Methods for Extruding Plastic Tubing, Inv. No. 337-TA-110, 218 U.S.P.Q. 248 (1982); Reclosable Plastic Bags, 192 U.S.P.Q. 674; Panty Hose, Tariff Commission Pub. No. 471 (1972).

The legislative history of Section 337 indicates that "where unfair methods and acts have resulted in conceivable loss of sales, a tendency to substantially injure such industry has been established." Trade Reform Act of 1973, Report of the House Comm. on Ways and Means, H. Rep. No. 93-571. 93 Cong. 1st Sess. at 78 (1973), citing In re Von Clemm, 108 U.S.P.Q. 371 (C.C.P.A. 1955). The Commission has discussed the meaning of tendency to substantially injure. In discussing the legislative history of section 337 the Commission noted in Optical Waveguide Fibers, Inv. No. 337-TA-189, that this "sentence is an apparent attempt to characterize the holding in Von Clemm, rather than a concurrent explanation of the provision relating to tendency to substantially injure. ... The majority opinion in Von Clemm did not explicitly refer to 'conceivable losses of sales' but affirmed the Commission's determination on tendency to injure which was made on the basis of ever increasing imports which undersold complainant's articles" Commission Decision at 13, 14, n.9.

The injury requirement has never been altered by Congress, and in fact Congress expressly rejected an attempt to eliminate this element from section 337 in the Trade Reform Act of 1973. Textron at 1029, citing H. Kaye, et al., International Trade Practice § 6.05 n.1 (1984) Although this legislative history suggests a low threshold with respect to the "tendency" language of section 337, the injury has to be of a substantive and clearly foreseen threat to the future of the industry, not based on allegation, conjecture, or mere possibility. In the Matter of Certain Braiding Machines, Inv. No. 337-TA-130 (1983); In the Matter of Expanded Unsintered Polytetraflouroethylene in Tape Form, Inv. No. 337-TA-4 (1976).

The tendency to injure standard is clearly met in this investigation. During February-July 1986, IN/US demonstrated its RITA chromatogram analyzer

C to potential customers. FF 362, 364. As evidenced by correspondence between IN/US and ISOMESS and the sales representatives of

C IN/US,

C

FF 367.

During January-June 1986, Radiomatic demonstrated its Model RS TLC

C analyzer to potential customers. FF 372, 378. As evidenced by

C inter alia the Radiomatic/Radioanalytic 1986 business plan,

C

C . FF 377.

For the above reasons, I determine that there exists a tendency to injure the domestic industry by reason of chromatogram analyzers imported into the United States by respondents IN/US and Radiomatic.

FINDINGS OF FACT

I. JURISDICTION

1. The Commission has jurisdiction over the parties in this Investigation. Two of the named respondents are domestic corporations engaged in the importation and sale of the products in issue in the United States. The two remaining respondents are foreign corporations, one Japanese and one German, engaged in the manufacture and/or exportation to the United States of the products in issue. The foreign respondents have entered general appearances in the investigation and have not challenged jurisdiction. CPX 164, Stipulation 1.

2. The Commission has jurisdiction over the subject matter of the investigation under 19 U.S.C. § 1337 because the alleged unfair acts and unfair methods of competition involve importation of chromatogram analyzers and components thereof into the United States. The chromatogram analyzers are sold in the United States. CX 164, Stipulation 2.

II. BACKGROUND

A. The Parties

3. Complainant Bioscan, Inc. ("Bioscan") is a corporation of the District of Columbia having its place of business at 4590 MacArthur Boulevard, N.W., Washington, D.C. 20007. CX 164, Stipulation 3.

4. Respondent Aloka Co., Ltd. ("Aloka") is a corporation organized under the laws of Japan with a place of business at 22-1 6-Chome, Mure, Mitakashiu, Tokyo 181, Japan. CX 164, Stipulation 4.

5. Respondent Radiomatic Instruments & Chemical Co., Inc. (Radiomatic") is a corporation of Florida having its place of business at 5102 S. Westshore Boulevard, Tampa, Florida. CX 164, Stipulation 5.

6. Respondent IN/US Service Corporation ("IN/US") is a corporation of New Jersey having its place of business at 1275 Bloomfield Avenue, Fairfield, New Jersey. CX 164, Stipulation 6.

7. Respondent ISOMESS Isotopenmessgerate GmbH ("ISOMESS") is a corporation organized under the laws of the Federal Republic of Germany with a place of business at Benzstr. 4, 7541 Straubenhardt, 1, Federal Republic of Germany. CX 164, Stipulation 7.

B. The Patent in Suit

8. The respondents are accused of unfair acts in the importation into and the sale of articles in the United States by reason of the accused infringement of U.S. Patent 4,019,057 ("the Bram patent"). CX 164, Stipulation 8; Complaint.

9. The Bram patent was issued to Institut Pasteur, as the assignee of the inventor, Stanley Bram, on April 19, 1977, for an invention entitled "Device For Determining The Spatial Distribution Of Radioactivity Within An Object." CX 164, Stipulation 9; CX 4; CX 6.

10. The Bram patent was filed in the United States on February 26, 1975, pursuant to 35 U.S.C. 119, based upon a French priority application filed on April 25, 1974. CX 164, Stipulation 10; CX 1; CX 4.

11. The applicant filed the priority application in an eligible foreign country. France affords similar priority privileges to applications first filed in the United States and is recognized as such by the United States Patent and Trademark Office (PTO). Manual of Patent Examining Procedure Section 201.13.

12. The United States application was filed within 12 months of the foreign priority application. Bram's United States and French applications were filed on February 26, 1975 and April 25, 1974, respectively. CX 3; CX 4.

13. The Bram United States application concerns a device adequately disclosed in the Bram French application. CX 3; CX 4.

14. The foreign application was for a "patent." Bram's French Patent Application No. 74.14453 was for a patent and eventually issued as French Patent No. 2,283,448. CX 3; CX 11.

15. Both the foreign and the United States applications were filed on behalf of the same inventive entity. Stanley Bram is the named inventor in both the foreign and United States applications. CX 3; CX 4.

16. Bioscan is the exclusive United States licensee of the Bram patent with the right to bring actions for infringement, and Bioscan has granted one sublicense to Laboratorium Prof. Dr. Berthold (hereinafter "Berthold"). CX 164, Stipulation 11; CX 7; CX 8.

17. The Bram patent is unexpired, and no court has declared it invalid or unenforceable. CX 164, Stipulation 12.

18. None of the respondents has been granted a license under the Bram patent. CX 164, Stipulation 13.

C. The Relevant Products

19. The products at issue in this investigation (hereinafter referred to as "imaging chromatogram analyzers") are electronic, radioactivity distribution imaging systems used primarily in biological and biomedical research for the quantitative analysis of samples which are radioactively marked or "labeled" with low energy beta emitting radioisotopes, primarily tritium (^{3}H), carbon 14 (^{14}C), and phosphorous 32 (^{32}P). CX 164, Stipulation 15.

20. Imaging chromatogram analyzers capable of detecting ^{3}H, ^{14}C and ^{32}P presently are sold in the United States only by Bioscan, Berthold (under license from Bioscan), and the respondents. CX 164, Stipulation 19; CX 163, Stipulations 1, 3.

21. Complainant Bioscan has manufactured and marketed an imaging chromatogram analyzer in the United States since 1980 when it sold its first analyzer, to the National Institute of Health (NIH). The NIH version was followed by the BID 100. Bioscan currently manufactures and sells in the United States System 200, 400, and 500 imaging chromatogram analyzers. The

systems sold by Bioscan have different computers and/or features and are sold at different prices, but they all have the same detector assembly. CPX 3, NIH Prototype; CPX 2, BID 100; CX 32, BID 200; CX 33, BID 400; CX 34, BID 500; Shulman, Tr. 125, 355, 377.

21a. Dr. Shulman was one of the founders of Bioscan, Inc. in 1980 and has been its president since that time. Shulman, Tr. 94, 126; CX 130.

22. Respondent IN/US presently markets in the United States an imaging chromatogram analyzer manufactured abroad for sale into the United States by respondent ISOMESS; the imported IN/US imaging chromatogram analyzer has been marketed in the United States since about January 1986, under the name Radioactivity Intelligent Thin-Layer Analyzer (hereinafter the "Isomess RITA"). CX 164, Stipulation 25.

23. Respondent Radiomatic markets in the United States an imaging chromatogram analyzer manufactured abroad by respondent ALOKA; the imported Radiomatic imaging chromatogram analyzer has been marketed in the United States since about April 1985, under the model designation Model RS Thin-Layer Chromatogram Scanner (Model RS). CX 164, Stipulation 26.

24. Low energy radioisotopes such as ^{3}H, ^{14}C, and ^{32}P are used extensively in biological research. Equipment for analyzing samples radioactively labeled with such isotopes is an important tool in biological and biomedical research. Both the distribution and quantity or radioactivity in a sample provide a researcher with valuable information, and the relative distribution of radioactivity in comparative samples is sometimes valuable. CX 164, Stipulation 16.

25. Imaging chromatogram analyzers are used to analyze radioactively marked samples on thin layer chromatograms, electrophoresis gels, and paper strips. The chromatogram, gel, or paper is placed on a sample holder which is placed under a radioactivity detector of the imaging chromatogram analyzer to electrically detect and analyze the spatial distribution of radioactivity in the sample. CX 164, Stipulation 17.

26. The imaging chromatogram analyzer detects and analyzes low energy radioactivity in a sample both in terms of its distribution and its quantity, with useful resolution for low energy isotopes such as ^{3}H, ^{14}C, and ^{32}P. CX 164, Stipulation 18.

27. An elongated conductor is mounted within and extends along the length of the detector chamber adjacent the opening in the bottom of the chamber. The sample is mounted on a flat sample support, the sample support and the detector chamber are brought together so that the sample lies directly beneath the opening in the chamber. The bottom of the chamber and the underlying surface formed by the sample and its holder are held in a fixed relationship so that, in the measuring position, the sample is mounted in the ionizable gas volume without a window between the sample and the electrode wire. CX 164, Stipulation 20.

28. The elongated conductor has properties that allow associated electronics to determine the position of a radioactivity decay event along its length. Also, the detector is constructed to operate as a proportional counter so that the radioactivity decay events produce signals proportional in amplitude to the amount of ionization of the gas caused by the radioactivity. The spatial distribution of radioactivity in the sample, i.e., the positions

and quantities of radioactivity events along the length of the sample, can be determined by the electronics associated with the electrode wire. CX 164, Stipulation 21.

29. The RITA, Model RS TLC scanner, and Bioscan BID chromatogram analyzer systems are position-sensitive proportional counters primarily intended for the measurement of soft beta radioactivity from ^{3}H, ^{14}C, and ^{32}P. CX 164, Stipulation 28; CX 162C, Stipulation 3, CX 162C, Stipulation 17; CX 163C, Stipulation 7.

D. <u>The Technology of the Products in Issue</u>

30. Chromatography can be used to separate and identify compounds. The position-sensitive proportional counters at issue can be used to quantitate the compounds. Reich, Tr. 5.

31. In thin-layer chromatography, a 2-inch by 8-inch glass plate coated with a layer of alumina or silica is typically utilized. The sample is then spotted on this plate for separation. Reich, Tr. 9.

32. There are many different ways of detecting chromatogram plates, but separation and quantitation always occur in one step. A classical graph results where the peak corresponds to the distance the substance has travelled, and the quantity of the compound can be determined by the area under the peak. Reich, Tr. 9.

33. The identification of a substance separated by chromatography is achieved by comparing the graph of the unknown to the graph of a standard. Reich, Tr. 9.

34. Organic compounds used in chromatography may be labeled by substituting radioactive markers into the compound, such as tritium (^{3}H) for hydrogen and carbon 14 (^{14}C) for carbon. Reich, Tr. 13.

35. Radioactive particles decay or decompose, emitting particles which often have a positive or negative charge. Reich, Tr. 36.

35a. The "beta particle," a negatively-charged electron, is the radioactivity species of primary concern in these discussions. Reich, Tr. 16.

36. Ionization is the process where a normally neutral atom loses or gains electrons and thus becomes charged. Reich, Tr. 36.

37. A beta particle, emitted from an atom through radioactive decay, is a single electron. The emitted particle almost never hits the detector wire. On its way through an ionizable gas, its kinetic energy is transferred into this gas by ionizing other molecules. Reich, Tr. 38.

38. Those beta particles travelling a further distance through the ionizable gas will produce more electrons than those traveling less distance. Reich, Tr. 38.

39. Gas multiplication is based upon the high voltage of a wire accelerating the gas ions coming near the wire. More ions are created during acceleration toward the wire. Reich, Tr. 38.

39a. There are several types of proportional counters including those where the sample is placed outside the chamber which has a thin wall to permit penetration of radiation ("thin window counter"), those where the sample is placed on a pan ("planchet") inside the chamber ("gas proportional detector"), and those where the counting chamber has a slit or opening in proximity to which the sample is placed and through which the gas is allowed continuously to exit ("windowless flow counter"). Shulman, Tr. 220.

40. Proportional counters, Geiger-Muller (GM) counters and spark chambers are all basically ion chambers. The difference between these four is the amount of high voltage that one applies to the electrodes and the kind of gas that is used. Reich, Tr. 17.

41. One of the major differences between ion chambers, proportional counters, Geiger-Muller (GM) counters and spark chambers is the differences in operating voltage. The operating voltage in the ion chamber is the lowest. The proportional counter has a higher voltage than the ion chamber. Next in voltage is the GM counter, and finally the spark chamber has the highest voltage. Reich, Tr. 18-21.

42. In the ion chamber region, there is little or no gas multiplication. In the proportional region, the multiplication is directly proportional to the kinetic energy of a beta particle. In the GM and spark regions, there is so much multiplication that pulses are large and relatively independent of the energy of the decay event which initiated them. Reich, Tr. 18-21; Borkowski Dep., CX 132 at 112-14.

43. The position-sensitive proportional chromatogram detectors at issue operate in the voltage range of 1,200 to 1,700 volts. Shulman, Tr. 324-25.

44. In a proportional counter, secondary electrons produced through ionization speed up as they get closer to the charged wire. As they speed up, they also bump into other gas molecules, and they create more ionized gas. By the time they reach the vicinity of the high voltage wire there is considerable charged effect. Reich, Tr. 19.

45. The Borkowski '377 patent describes how to find the point on the wire where the electrons impinge upon it. This is done by constructing the wire out of a high resistance material so the electronic signal will move slower than normal. On a nonresistive wire, the approximate travel time for this signal would be 0.0005 microseconds on a 20 centimeter wire. With the Borkowski high-resistance wire this travel time is reduced to 5 microseconds for a 20 centimeter wire. The time of arrival at both ends of the wire can be determined, and with appropriate electronic circuitry, the position of the particle on the wire can be determined. Reich, Tr. 26-27.

46. The average energy of a tritium particle is about five kilovolts. The average range of tritium particle in an argon-methane gas mixture is 0.2 or 0.3 millimeters. Tritium as a low energy ionizing particle. Borkowski, Tr. 682.

47. Teaching of the principle of gas multiplication in proportional counting was well-known in 1974 and goes back more than 50 years. Rothberg, Tr. 450.

48. The initial ion pair generated by an alpha or beta particle, or gamma ray or an x-ray results in the same effect on the detector wire of a proportional counter. Borkowski Dep., CX 132 at 111-12.

49. There is a difference in the number of ion pairs produced by different types of particles called specific ionization. An alpha particle will produce approximately 1000 ion pairs per millimeter of path, whereas a beta particle will only produce 50 ion pairs. Borkowski Dep., CX 132 at 112.

III. PATENT VALIDITY

A. Patent Witnesses

50. Dr. Gerald Rothberg testified as an expert witness in radiation detectors. Rothberg, Tr. 395, 396-494.

51. Dr. Rothberg as a Ph.D. in Physics from Columbia University and is currently the head of Department of Materials and Metallurgical Engineering at Stevens Institute of Technology. Rothberg Dep., CX 134 at 4-5; RX 57.

52. Mr. Edward Polic testified as an expert witness in radiation detectors. Polic, Tr. 395, 494-607.

53. Mr. Polic has a Bachelor of Science degree in Electrical Engineering and a Masters of Business Administration. From 1957 to 1978, Mr. Polic was employed with the Packard Instrument Company, Inc. ("Packard"). During this time, he was involved in the design, production and sale of various types of radiation detectors. RX 57.

54. Mr. Casimir Borkowski testified as an expert in radiation detectors. Borkowski, Tr. 395, 661-97.

55. Mr. Borkowski has a Bachelor of Science degree in Chemistry from the University of Chicago. Mr. Borkowski worked at the Oak Ridge National Laboratory ("ORNL") from 1943 to 1977. After 12 years in the Chemistry Division at ORNL, he became Director of the Instrumentation and Controls Division of ORNL. Mr. Borkowski also directed and conducted research in the Basic Measurement Science Group within his Division. Borkowski, Tr. 661-62; RX 57; Kopp Dep., RX 56 at 8, 20.

56. Dr. Seth Shulman testified as a technical expert and fact witness on behalf of complainant. Dr. Shulman has an undergraduate degree in chemistry and physics and a doctor's degree in physics. He has had extensive experience with the design and use of radiation detectors since about 1967, first in research at Columbia University and later at the Naval Research Laboratory (NRL). Shulman, Tr. 94-95; CX 130.

56a. Dr. Shulman is familiar with all of the commercial imaging chromatogram analyzers. He is also familiar with the prosecution history of the Bram patent and actually participated in its reexamination. Shulman, Tr. 136, 172-73, 178-79.

57. Mr. Manfred Kopp testified as a fact witness with respect to research he conducted at ORNL and certain patents and publications co-authored by himself and Mr. Borkowski. Kopp, Tr. 620-60.

58. Mr. Kopp has a Master's Degree in electrical engineering (Kopp Dep., RX 56 at 50). He works in the Basic Measurement Science Group of the Instrumentation and Controls Division at ORNL. Mr. Kopp has worked at ORNL for over 20 years and was associated with Mr. Borkowski at ORNL from 1967 to about 1982. Mr. Kopp was a co-inventor on the Borkowski and Kopp '377 patent

58a. Edwin Greenblatt's deposition testimony was offered by complainant and was admitted into evidence without objection. Mr. Greenblatt has a degree in chemistry and is a sales engineer employed by respondent IN/US. He has been employed by IN/US or predecessor companies since 1968 and presently is involved in selling liquid scintillation counters and imaging chromatogram analyzers. Greenblatt Dep., CX 135 at 5, 9-10.

58b. Prior to 1968, Mr. Greenblatt was employed for 10 years by Packard Instrument Company. At Packard, he was a sales engineer involved in selling liquid scintillation counters and mechanical chromatogram scanners. Greenblatt Dep., CX 135 at 7, 8, 19.

58c. Mr. Greenblatt was familiar with Bioscan as early as 1979. He is familiar with the first Bioscan prototype (the NIH "box" prototype, CPX 3) and with subsequent Bioscan products. He sold Bioscan imaging chromatogram analyzers from about 1981 to 1986 while IN/US was a Bioscan sales representative. He is a stockholder in Bioscan and was at one time a director. Greenblatt Dep., CX 135 at 11, 12, 14, 15, 18; Kopp, Tr. 620-22.

B. Background of the Bram Invention

59. The Bram patent relates generally to the field of chromatography but in particular to an instrument for analyzing radioactive substances more rapidly and accurately than prior art chromatogram analysis equipment. CX 4, col. 1, lines 11-52; col. 4, lines 8-14, 19-21; col. 9, lines 1-9; Rothberg Dep., CX 134 at 67-68.

60. Chromatography is a separation process used by researchers to separate different components of mixtures so they can be identified and quantified. This process is performed by allowing the different components of the mixture to migrate for a certain time period along an absorbent support. Because the different components move at different speeds, the components are naturally separated and are located at different spots on the support at the end of the time period. Reich, Tr. 5-6; Prydz article, CX 2 at 16, col. 1.

61. Thin layer chromatography (TLC) of radioactively labeled substances, the subject of the devices in this investigation, involves using the chromatographic separation process to separate radioactively labeled components of a mixture along one or more lanes on a thin support such as a flat sheet of glass or paper strip. Reich, Tr. 8; CX 164, Stipulations 15, 16.

62. A radioactively labeled TLC sample (hereinafter a "thin layer chromatogram"), typically is a thin flat, glass or paper support with one or more parallel lanes, along the length of which different radioactively labeled components of mixtures have been separated. Some of the lanes may contain known mixtures or components for reference purposes. Thin layer chromatogram samples typically are labeled with low energy radioisotopes such as tritium (^{3}H), carbon 14 (^{14}C) or phosphorous 32 (^{32}P). These radioisotopes, separated on a TLC plate, present "spots" of low energy radioisotopes distributed along a chromatogram lane. Reich Tr. 9-11; CX 4, col. 5, lines 3-10; CX 164, Stipulations 15, 16.

63. Radioisotopes used in chromatography are "isotropic sources" in the sense that they emit radioactivity uniformly in all directions. Radiation from spots on a thin layer chromatogram sample therefore is emitted perpendicular to the TLC plate and at all other angles, as opposed to a collimated source which screens out all radiation except in only one direction, e.g., perpendicular. Shulman, Tr. 295; CX 156.

64. Thin layer chromatography is used extensively in biological and biomedical research to test and develop new drugs and the like. For example, a test animal may be fed a new drug labeled with a low energy radioisotopes such as ^{3}H, ^{14}C, or ^{32}P. The drug is metabolized by the

animal, and radioactivity accumulates in various parts of the animal. Those parts, in liquid phase, are subjected to thin layer chromatography to produce the above-described samples with components separated along chromatogram lanes. From the analysis of the position and quantity of radioactivity events along each lane, the researcher can draw valuable conclusions about the effectiveness of the drug, how to make it more or less powerful, etc. Reich, Tr. 14-15; CX 136 at 275; Prydz article, CX 2, at 16, col. 1.

65. One of the early ways of analyzing thin layer chromatograms was to place a photographic plate, e.g., an X-ray film, in contact with the chromatogram for a long period and then develop the photograph. Dark spots on the developed photograph would indicate the positions of radioactivity in the sample. This method called "autoradiography" suffers from lengthy exposure times and is inapplicable when a wide range of radioactivity and double labeled samples are present. Also, after the spots are developed there is still a need for further lengthy analysis, and quantification nevertheless is poor. Reich, Tr. 16; CX 136 at 277, 279, 283; CX 4, col. 1, lines 13-18, lines 40-43; Prydz article CX 2, at 16, col 1; IN/US Memorandum CX 42, at 2.

66. A widely used technique for TLC analysis has been liquid scintillation counting. In this method, small sections of thin layer chromatograms are scraped off the TLC plate and placed in a scintillation counter which counts radioactivity events by detecting light produced when radioactive emissions interact with scintillators mixed with the sample. The resolution is a function of the number and size of the sections scraped from the plate. This method is extremely tedious and time consuming, particularly when small sections are used to obtain adequate resolution. Further, if a

large number of samples are to be analyzed, liquid scintillation counting is subject to numerous sources of error. CX 136 at 284; CX 4, col. 1, lines 28-30, lines 47-52; IN/US Memorandum CX 42, at 2.

67. Quantitative evaluation of thin layer chromatograms by direct scanning has included the use of ion chambers, Geiger counters, proportional counters, and spark chambers. In such devices, direct measurements are made from the TLC plates by detecting ionization produced by radioactivity events. Detection methods have included electrical detection (e.g., Berthold and Packard windowless scanners) and film development (e.g., spark chamber Beta Camera made by Berthold and Aloka). Mechanical strip scanners were also once widely used. Reich, Tr. 15-17; CX 136 at 290; CX 136 at 290, 293, 295; CX 4, col. 1, lines 30-36; see also, CX 2, Kaplan, et al. article (multi-wire proportional counter), Pullan et al. article (spark chamber), Prydz article (windowless mechanical scanners and Beta camera); CX 67 (Aloka Beta Camera); IN/US Memorandum, CX 42, at 2.

68. The 1978 edition of Touchstone et al., Practice of Thin Layer Chromatography, reported that the main methods of detection for radioisotope-labeled chromatograms were autoradiography (exposing the chromatogram to X-ray film for several hours or several days to weeks) liquid scintillation counting (scraping small sections of the sample off the plate), and less sensitive direct detection with spiral cathode spark chambers and point-by-point mechanical scanners. CX 136 at 277 (autoradiography), 284 (liquid scintillation), 290-93 (spark chambers), 293-98 (mechanical scanners, less sensitive at 297).

69. The problems associated with the use of gas-tight sealed chambers for the detection of low-energy radiation were as follows:

a. the inconvenience, difficulty, and expense of flushing the chamber with air after each use;

b. the contamination of the chamber with air after the introduction of the sample; and

c. the limited number of samples that could be tested during a period of time because of the time spent flushing the chamber. Abstract, RX 4, cols. 1, 2.

70. Mechanical scanners were often used to determine the location of radioactive spots with other means used to count the radioactivity. Polic Dep., CX 133, at 33, lines 6-10.

71. Mechanical radiochromatogram scanners are seldom sold today since there is little demand. Greenblatt Dep., CX 135, at 22-23; Shulman Tr. 148.

72. The 1983 edition of Touchstone et al., Practice of Thin-Layer Chromatography, mentions the Berthold TLC Linear Analyzer (an imaging chromatogram analyzer licensed under the Bram patent) and states that its major advantage over the mechanical scanners is that of speed, 100 times faster. CX 137 at 295-96.

C. The Bram Invention - Claim 5

73. The Bram patent discloses and claims an apparatus designed to analyze the quantity and distribution of radioactivity in chromatograms in which low energy, isotropic radiation sources are present on the surface of a TLC plate or paper sample. Shulman, Tr. 156-57; CX 4, col. 1, lines 11-52, col. 3, lines 3-8, col. 9, lines 38 to col. 10, line 5 (claim 5).

74. The objective of the Bram patent and the subject imaging chromatogram analyzers is to rapidly, accurately, and non-destructively determine the quantity and position, i.e., the spatial distribution or "image," of low energy radioisotopes, simultaneously along the entire length of a chromatogram lane, with high resolution and counting efficiency for the different radioisotopes used to label substances separated by thin layer chromatography. Reich, Tr. 8; CX 4, Abstract; CX 4, col. 1, lines 11-52 (chromatography), col. 3, lines 3-8 (tritium and carbon 14), col. 4, lines 11-14 (resolution), lines 19-21 (counting efficiency), lines 29-33 (apparatus), col. 9, lines 1-6.

75. Bram's detector is based upon the principles of position sensitive proportional counters in which the anode wire is at a high voltage, on the order of 1300 volts, and the detector chamber contains an ionizable gas. In such a counter, radiation traveling through the gas ionizes the gas creating free electrons. The electrons are drawn to the anode and are multiplied by well known gas multiplication principles to produce a detectable pulse. Shulman, Tr. 157; Rothberg, Tr. 464, 469-70; Polic Dep., CX 133, at 66-67, 88; CX 4, col. 6, lines 14-24.

75a. Improvements and modifications claimed by Bram over Borkowski and Kopp included placement of the object to be measured within the detector chamber and hermetically sealing it prior to filling with counting gas at beyond atmospheric pressure. A variation shown in the Bram patent involved placement of the object on the exterior of the chamber directly against a thin Mylar window to allow entry of emitted radiation, the underside of the window having been aluminized to be conductive (Shulman Dep., at 42). Bram claimed that pulse height analysis of pulses on the detector cathode could be used to eliminate those radiations substantially deviating from the perpendicular, thereby improving resolution. RX 10.

76. To analyze a chromatogram lane labeled with the most common radioactive markers, particularly tritium (^{3}H), the surface of the plate or paper on which the chromatogram sample is deposited must be inside the sensitive gas volume of the detector chamber, i.e., the detector chamber must extend to the surface of the chromatogram sample. Specifically, the ionizable gas must be free of air or other impurities and extend to the surface of the sample to produce ionization by low energy radiation near the surface of the sample, and the electric field created by the anode must extend to the surface of the sample to collect the free electrons resulting from gas ionization. Shulman, Tr. 121, 123-24, 258; Rothberg Dep., CX 134 at 57; Borkowski Dep., CX 132 at 34, 58, 88, 131.

77. If air gets into the sensitive gas volume of the detector chamber between the chromatogram and the detector wire, an imaging chromatogram analyzer cannot operate. CX 35 at 6.

78. The elements of claim 5 include a detector with a completely enclosed chamber, an ionizable gas in the chamber, and an elongated anode conductor wire so as to operate as a position sensitive proportional detector. At least a portion of one wall of the chamber is removable to permit mounting of the sample inside the sensitive gas volume of the chamber, and a support is attached inside the chamber to mount the sample in the gas volume in close proximity and substantially parallel to the anode wire. Means are provided for determining and displaying position and quantity of

radioactivity along the length of the anode wire. CX 4, Claim 5; Proposed Findings of Fact at 46, 47.

79. In the embodiments of Figure 2a and 2b, the chamber is sealed and the chamber is pressurized beyond atmospheric pressure. Pressurization and modification of the electronics of Kaplan's prior art devices are the means Bram uses to further improve the resolution for some radioisotopes such as ^{14}C. CX 4, col. 6, lines 33-38, col. 9, lines 6-9; Borkowski Dep., CX 132, at 152.

D. No Anticipation of the Bram Patent

80. In Dr. Shulman's opinion, the position-sensitive Geiger-Muller counter described in the 1971 article by De Lima and Pullan (CX 77) does not have all the elements of the Bram patent. Shulman, Tr. 151.

81. The counter described by De Lima and Pullan (CX 77) functions in the Geiger-Muller region rather than in the proportional regions. Because it is a Geiger-Muller counter, all pulses on the anode are of equal amplitude and the counter cannot discriminate against different pulse amplitudes as in Bram. The performance parameters of the De Lima and Pullan counter also suggest that the device would not yield satisfactory resolution in radiochromatogram analysis. Shulman, Tr. 151-56; CX 77.

82. The discussion of prior art in the specification of the Bram patent relates to proportional counters. Bram discusses modifications to Borkowski's one-dimensional proportional counter and Kaplan's two-dimensional proportional counter. Rothberg, Tr. 451.

83. The Geiger-Muller counter of De Lima and Pullan (CX 77) cannot achieve pulse-height analysis as claimed by Bram because all the pulses in a Geiger-Muller counter register at the same height. Shulman, Tr. 318; Rothberg, Tr. 452.

84. Neither a spark chamber nor a Geiger-Muller counter provides any kind of pulse-height information. Rothberg, Tr. 482.

85. Although De Lima and Pullan (CX 77) suggest that their device may have application to radiochromatography, Dr. Shulman does not believe that spiral-wound cathode Geiger-Muller counters have ever been used for chromatogram analysis. Shulman, Tr, 156; CX 77 at 79.

86. The resolution of the Geiger-Muller counter of De Lima and Pullan (CX 77) is quite poor in comparison to the degree of resolution that can be achieved in a proportional counter. Shulman, Tr. 318, 321-22; CX 77.

87. In Dr. Shulman's opinion, Geiger-Muller counters are much less useful than proportional counters for obtaining positional information from a radioactive sample. Almost all imaging systems are proportional counters. Shulman, Tr. 315.

88. After the experiments with a simulated chromatographic plate and ^{14}C samples in 1970 and 1971, no further work was done at ORNL in chromatography or ^{14}C detection until 1981. Kopp, Tr. 651-52.

89. Borkowski and Kopp never published the details of their 1970 experiment involving the position-sensitive detection of ^{14}C spots on a simulated chromatographic plate. Kopp, Tr. 655-57.

E. Scope and Content of the Prior Art

1. Enclosed Proportional Counters.

90. U.S. Patent 2,590,925 for a "Proportional Counter" issued to Borkowski and Fairstein on April 15, 1952. RX 3. This patent discloses a conventional proportional counter, specifically adapted for measuring low energy beta emitting samples, such as ^{14}C. The sample is introduced directly into the chamber by means of a plunger-like sample platform. There is a longitudinally disposed anode wire within the enclosed chamber. RX 3.

91. Closed-chamber, conventional proportional counters are described in U.S. Patent 2,917,634, issued to Barnothy on December 15, 1959 (RX 4); U.S. Patent 2,917,648, issued to Davidson on December 15, 1959 (RX 5); U.S. Patent 3,155,829 issued to Frank on November 3, 1964 (RX 6); and U.K. Patent 831,545, issued to Atomic Energy of Canada Limited, published on March 30, 1960 (RX 9).

91a. All three detectors of RX 39 are completely enclosed proportional counters with the radiation source outside and with either a solid wall (detector 1) or an aluminized mylar window between the source and the detector chamber. All three were used in experiments with X-rays and/or collimated alpha particles (Figure 12). RX 39 at 343; see also, "Applications" at 343-44.

92. The principles of closed-chamber, conventional proportional counters are described in publications by Borkowski in 1949 (RX 12); W.J. Price in 1958 (RX 29; and Wang and Willis in 1965 (RX 29).

93. Mr. Borkowski and co-workers used ^{3}H as a tracer in their radiation detector experiments in the biology and chemistry divisions at ORNL during the early 1970's, and Mr. Borkowski discussed the detection of ^{3}H as early as 1949 in a paper published in Analytical Chemistry (RX 12). Borkowski Dep., CX 132 at 59-60.

94. Dr. Shulman testified that he knew Borkowski and Kopp had worked with the detection of ^{3}H and ^{14}C samples. Shulman, Tr. 330.

95. The Basic Instrumentation Group at ORNL was charged with doing basic research and developing new ideas, new techniques and determining the fundamental properties of detectors, primarily detectors for the measurement of nuclear radiation. It was in this Group that Borkowski and co-workers first developed proportional counters, and eventually developed essentially the same detectors as position-sensitive detectors. Borkowski, Tr. 662; Borkowski Dep., CX 132 at 81.

96. Mr. Borkowski first became interested in measuring ^{3}H and ^{14}C in about 1946. He realized that he could detect a single ion pair in the sensitive gas volume of a proportional counter by using the gas multiplication process. Borkowski, Tr. 663.

97. The first time that Borkowski and Fairstein disclosed that ^{3}H and ^{14}C could be detected inside the sensitive gas volume of a proportional counter was in a 1946 article in the Bulletin of American Physical Society. Borkowski, Tr. 665-66; RX 12, Ref. 1.

98. Figure 1 of the '925 patent to Borkowski and Fairstein, issued in 1952 (RX 3), depicts a conventional proportional counter with a high voltage anode wire for sensing the pulse generated from one ion pair through

secondary multiplication of the electron energy. Because the detector could detect one ion pair, it could measure the energy from low energy beta sources such as ^{3}H and ^{14}C when the radiation source was placed inside the sensitive gas volume of the counter. Borkowski, Tr. 663-65; RX 3; RPX 9.

99. The sample support shown in Figure 1 of the '925 Borkowski and Fairstein patent (RX 3) can be adjusted up and down to varying heights within the rectangular chamber of the proportional counter. When adjusted up and down, the sample support can be positioned parallel to the bottom of the counter chamber, or above or below that plane. In any of these positions, the sample support is within the sensitive gas volume of the counter. Borkowski, Tr. 663-65, 680-81; RX 3; RPX 9.

100. In Mr. Polic's opinion, the sample support of Figure 1 of the '925 Borkowski and Fairstein patent (RX 3; RPX 9) becomes an <u>internal</u> sample support if it is moved upward by means of an adjustable screw so as to protrude into the rectangular interior of the counting chamber. Polic, Tr. 606-07.

101. The 1949 article by Borkowski (RX 12) discusses voltage plateau in proportional counters. RX 12 at 348-49.

102. The 1958 article by Price (RX 29) discusses the appropriate voltages to be impressed on the anode wire of a proportional counter. RX 29 at 148-150.

2. <u>Windowless Proportional Counters</u>.

103. Several papers prior to 1974 dealt with the use of windowless proportional counters in radiochromatography applications. Rothberg, Tr. 417.

104. The 1962 article by Schulze and Wenzel (RX 17) describes a gas-flow proportional counter with a windowless slit. The detector was used to mechanically scan a chromatogram. Performance figures for the counting efficiency of ^{14}C and ^{3}H are given on page 581 of the article. Schulze and Wenzel disclose counting efficiencies of 40 percent for ^{14}C and 0.3 percent for ^{3}H. RX 17; Rothberg, Tr. 418-19.

105. A 1965 paper published by F. Berthold, entitled "Recent Methods for the Automatic Evaluation of Thin-Layer and Paper Chromatograms of Labeled Substances" (RX 27) discloses the use of a gas-flow, windowless (slit) detector, with mechanical scanning means for two-dimensional scanning, adapted specifically for measuring low energy ^{3}H and ^{14}C samples used in biomedical research. In his paper, Berthold stresses the importance of operating without a window for measurement of ^{3}H samples. He further indicates that he used his counter in the proportional range. RX 27.

106. In the 1965 paper by Berthold (RX 27), it is observed that there is a region of virtual distance independence of counting sensitivity when a chromatogram sample of ^{3}H is positioned under a windowless radiochromatogram scanner. With respect to the distance between the chromatogram sample and the bottom of the counting chamber, there is very little variation in counting sensitivity between 0.5 and 2 millimeters. Because of the counter parameters, "the electrical field extends through the opening in the diaphragm into the space between counter and chromatogram, thereby pulling negative charge carriers produced by ionizing radiation even outside the counter volume into the region of gas amplification and around the anode wire." RX 27 at 303, 306-07; Polic, Tr. 556-58.

107. The 1965 paper by Berthold (RX 27) describes a gas-flow, windowless proportional counter capable of detecting ^{3}H or ^{14}C on a thin-layer chromatogram. Shulman, Tr. 363-64; Polic, Tr. 558; RX 27 at 305-06, 313.

108. The 1965 article by Berthold (RX 27) discusses the appropriate distance for placement of a ^{3}H radiochromatogram outside a windowless detector. Shulman, Tr. 296; RX 27.

109. A 1973 brochure of the Packard Instrument Company illustrates and describes the Packard Model 7201 windowless strip scanner for radiochromatograms. RX 42.

110. The Packard Model 7201 Radiochromatogram Scanner was capable of measuring ^{3}H or ^{14}C on a chromatogram paper strip or plate. This windowless proportional counter had a counting efficiency of one percent to two percent for ^{3}H. The bottom of the chamber was open and collimators could be positioned between the sample and the counting chamber. The total height of the chamber was about 7 to 10 millimeters, and the distance from the anode wire to the bottom of the chamber was about 1 to 3 millimeters. Polic, Tr. 511-14; RX 42.

111. The Berthold strip scanner of circa 1970-1974 was very similar to the Packard Model 7201. It used a windowless flow counter to count ^{3}H and ^{14}C from radiochromatographic strips. Polic, Tr. 514, 556-58; RX 27; RX 32.

112. A windowless proportional counter is described in U.S. Patent 3,603,831, "Radiation Detector With Gas-Permeable Radiation Window," issued to Kimmel on September 7, 1971. RX 2.

113. The '831 Kimmel patent (RX 2) discloses the use of a windowless proportional gas-flow counter for detecting ^{3}H. Kimmel's objective was to replace the normal detector window with a wire screen more permeable to low energy radiation. RX 2; Polic, Tr. 521-22.

113a. The '831 Kimmel patent is classified under subcategory 83.6 of category 250. RX 2.

114. Windowless proportional counters are described in detail in publications by H.E. Dobbs in 1964 (explains that gas-flow proportional counters of the windowless variety are particularly suited to radiochromatography using weak beta particles) (RX 15); Shulze and Wenzel in 1962 (discusses the advantages of windowless flow counters over liquid scintillation methods) (RX 17); Berthold and Wenzel in 1967 ("Obviously ^{3}H . . . is the most difficult to measure . . . . windowless measurements are required in the case of ^{3}H.") (RX 32); Ravenhill and James in 1967 (RX 18); P.F. Wilde in 1964 (RX 19); W.J. Price in 1958 (RX 29); and Wang and Willis in 1965 (RX 30).

115. The 1973 article by Prydz considered by the Patent Office during the reexamination of the Bram patent (CX 2) discusses the use of windowless gas-flow Geiger-Muller tubes for radiochromatogram scanners. Prydz, CX 2 at 17-19; Shulman, Tr. 138.

116. When the sample being measured in a windowless counter is relatively close to the counter opening, both the sensitive gas volume and electric fields extend down to the sample itself, thus ensuring good counting efficiency. Polic, Tr. 557; RX 27; RX 32.

117. The average path length of a tritium particle is very short, somewhere around 0.5 millimeters, with the maximum path length for tritium in air being approximately 2 millimeters. The ion pairs formed by tritium ionization have very little kinetic energy and the electrons resulting from this ionization migrate essentially straight up to the anode wire. Thus, for tritium detection, the depth of the detector chamber and the distance of the anode from the sample are not critical to resolution. Polic, Tr. 550-54; SX 13.

3. <u>Position-Sensitive Proportional Counters</u>

118. U.S. Patent 3,483,377 for a "Position-Sensitive Radiation Detector," issued to Borkowski and Kopp on December 9, 1969. (RX 1). The '377 patent to Borkowski and Kopp teaches the modification of "an otherwise conventional detector" into a position sensitive proportional counter. This is accomplished by simply "inserting a very high resistance collector in an otherwise conventional detector." Borkowski explains that "[t]he rise time of any pulse therefrom is thereby position-sensitive, but energy independent." RX 1, col. 1, lines 13-16.

119. The '377 patent to Borkowski and Kopp, issued in 1969 (RX 1), is the result of early work by Borkowski and Kopp on the localization of radioactivity in a proportional counter. The '377 patent discloses the use of the high resistance anode wire and rise-time measurement of the pulses on the anode to determine position of radioactivity. In order to make their counter position sensitive, Borkowski and Kopp merely substituted the highly conductive anode wire found in a conventional proportional counter with a highly resistive carbon quartz wire. Borkowski, Tr. 667-68; RX 1.

120. One of the objectives of the '377 patent (RX 1) was to provide a position-sensitive detector more sensitive to low energy ionizing particles. RX 1, col. 1, lines 26-27. Mr. Borkowski testified that the phrase "low energy ionizing particles" as used in the '377 patent included ^{3}H and ^{14}C, as well as other low energy beta particles, alpha particles, and positrons. However, neutrons would not be included because they are not ionizing particles. Borkowski, Tr. 669-71.

121. The reference to "low energy ionizing particles" in Borkowski and Kopp's '377 patent (RX 1) was intended to refer to ^{3}H and ^{14}C beta particles. Kopp Dep., RX 56 at 59-60; RX 1, col. 2, lines 26-27.

122. Prior art discussions of position sensitive proportional counters include publications by Borkowski and Kopp in 1968 (RX 16); and Borkowski and Kopp in 1979 (RX 39).

122a. 1972, Gabriel and Dupont, described the use of a PSPC, based upon the design of Borkowski and Kopp (RX 16), for X-ray crystallography. The detector had a thin aluminized Mylar widow to permit the entry of Fe-55 X-rays. "This counter is built like a classical proportional detector . . ." but with a high resistance anode wire; spatial information was obtained using risetime circuitry. RX 14.

122b. In March 1974, Gabriel and Bram described the use of PSPC, based upon the design of Borkowski and Kopp (RX 16), for counting of ^{14}C. The counting chamber had a thin aluminized mylar window on which one-dimensional paper electrophoretograms were directly placed for measurement. Although Gabriel and Bram discussed only electrophoresis, possible application to chromatography is cited. RX 13; Shulman, Tr. 194-95.

123. In the gas-flow, position-sensitive prototype detector denominated "Detector No. 5" in the 1968 article of Borkowski and Kopp (RX 16), a collimated alpha particle source was injected into the counter chamber through a hole in the counter wall. Kopp Dep., RX 56 at 61; RX 16 at 1516.

124. An article by Kaplan et al., entitled "Multi-wire Proportional Chambers for Biomedical Applications," published in Nuclear Instruments and Methods in 1973 (RX 25), describes multi-wire proportional counters incorporating delay-line electronics. The counters have windows and are adapted "for a variety of biomedical applications including X-radiography, neutron radiography, and radioisotope imaging." RX 25 at 397. Spatial resolution in two dimensions is accomplished as follows: "The coordinates of an ionizing event are determined by the use of electromagnetic delay lines capacitively coupled to each of the orthogonal planes of ground grid wires." RX 25 at 398.

125. The 1973 Kaplan et al. article (RX 25) discloses a multi-wire, two-dimensional position-sensitive proportional counter with a window. Among the biomedical applications cited by Kaplan for this counter is radioisotope chromatography. RX 25 at 397; Polic, Tr. 547.

125a. In writing of the Kaplan device, Bram acknowledged "Their device may effectively be used to measure low resolution autoradiograms of ^{14}C and ^{3}H in two dimensions. . ." Col. 3, lines 49-51. Kaplan made use "of the proportional feature of these chambers in order to discrimination against unwanted radiations," (Polic, Tr. 546) and provided lower-level and upper-level discriminators for that purpose. Polic, Tr. 583-84.

126. Multi-wire proportional counters are described in U.S. Patent 3,786,270 issued to Borkowski and Kopp on January 15, 1974 (RX 7); and U.S. Patent 3,917,279 issued to Giulland and Emming on October 7, 1974, based upon an application filed on May 17, 1973. RX 8.

127. The proportional counter photon camera of RX 40 is the same as that described in the '270 patent to Borkowski and Kopp (RX 7). The multi-wire, position-sensitive experimental detector of RPX 10 was a precursor of the photon camera described in RX 7 and RX 40. Kopp, Tr. 629; Kopp Dep., RX 56 at 19-20.

128. The experimental detector of RPX 10 is described in a 1970 IEEE Transactions paper by Borkowski and Kopp. RX 39. The detector is described as "Detector 3" on page 343 of this article. RX 39 at 343; Kopp, Tr. 637; Kopp Dep., RX 56 at 22, 57-58.

129. Multi-wire proportional counters are also discussed in articles published by Charpak et al. in 1968 (RX 20); Westphal in 1972 (RX 21); and Borkowski and Kopp in 1972 (RX 40).

4. Energy discrimination.

129a. The 1972 IEEE paper by Borkowski and Kopp (RX 40) describes a position sensitive, proportional counter "photon camera" using the Borkowski and Kopp '377 patent method for determining position by rise time measurements. RX 40 at 1, col. 1, "Abstract."

130. The 1972 IEEE Transactions paper by Borkowski and Kopp entitled "Proportional Counter Photon Camera" (RX 40) discloses the use of "energy discrimination" for background reduction. Mr. Kopp testified that the

energy discrimination circuitry in this proportional counter was used to reject unwanted background and to improve resolution of the image. RX 40 at 1; Kopp, Tr. 642; Kopp Dep., RX 56 at 37-38; Rothberg, Tr. 443.

131. At the time Messrs. Borkowski and Kopp described the use of "energy discrimination" in their 1972 IEEE Transactions paper (RX 40) and in their 1971 Program and Budget Proposal (RX 38), it was already well known that one could discriminate among different energies based upon pulse height using a voltage discriminator. By operating the voltage discriminator at some present level, one could discriminate against pulses that were larger than that threshold setting. Borkowski, Tr. 675-77; RX 40 at 1; RX 38 at 3.

132. The 1973 article by Kaplan et al. (RX 25) discloses the use. of pulse-height discrimination in a proportional counter to improve resolution. Polic, Tr. 546-47; RX 25 at 397, 404; CX 1.

133. The 1973 Kaplan et al. article states that "[w]e also make use of the proportional feature of these chambers in order to discriminate against unwanted radiations." Kaplan et al. go on to state that "[f]or such purposes we . . . exclude any of the negative gases which enhance the multiplication and produce larger signals at the cost of energy discrimination." Figure 15 of the Kaplan article discloses the use of pulse-height discriminator circuits in conjunction with a multi-wire proportional counter. RX 25 at 397, 404; Polic, Tr. 546.

134. Circuitry such as that described by Kaplan et al. (RX 25) for rejecting angular-generated pulses from secondary ionization is as applicable to electrons generated by low-energy beta particles as it is to electrons generated by gamma rays. Polic, Tr. 593-94.

5. Collimators.

135. There were many references to the use of collimators in radioisotope detection prior to 1974. Rothberg,Tr. 411.

136. In Dr. Shulman's opinion, it was well known in 1974 that one could use a mechanical collimator to improve resolution in radiation detection. Shulman, Tr. 307-08.

137. In their 1972 IEEE Transactions paper, Borkowski and Kopp disclose the use of mechanical collimators for improving spatial resolution in radioactivity detectors. RX 40 at 1; Rothberg, Tr. 441. A similar collimator is disclosed in the '270 Borkowski and Kopp patent. RX 7, col. 2, line 58 to col. 3, line 11.

138. The 1973 article by Kaplan et al. discloses the use of a parallel-hole collimator to improve resolution in a two-dimensional position-sensitive proportional counter. Polic, Tr. 571; RX 25 at 404-05.

139. A 1973 brochure for the Packard Model 7201 Radiochromatogram Analyzer discloses the use of adjustable collimators for controlling the resolution between adjacent spots on a radiochromatogram. The collimator permits the detection of only those tracks substantially perpendicular to the anode wire. Angular tracks are eliminated, thereby improving spatial resolution. RX 42 at 2; Rothberg, Tr. 441-42.

140. With respect to the four different collimators used on the Packard Model 7201 Radiochromatogram Scanner, there is a direct relationship between the width of the collimator selected and the resolution achieved. Polic, Tr. 560-62, 596-97; RX 42.

F. Differences Between Bram and Prior Art

141. Claim 5 of the Bram patent reads as follows:

> In an apparatus for determining the spatial distribution of the radioactivity in an object, the combination comprising a detector having a completely enclosed chamber containing a ionizable gas, at least a portion of one wall of said chamber being removable, an elongated conductor extending longitudinally of and fixedly secured within said chamber, a support attached inside said chamber to said chamber walls in close proximity to said elongated conductor, said support being adapted to mount said object in close proximity and substantially in parallel to said elongated conductor, means operatively connected to said elongated conductor for determining the location along said elongated conductor of radioactive particles emitted by said object and reaching the proximity of said location, means connected to said determining means for counting the number of said particles at each one of a plurality of said locations, and a display device connected to the output of said counting means.

CX 4.

142. Claim 8 of Bram calls for the apparatus of claim 5, further comprising a collimator placed between the radioactive object and the anode detector wire. CX 4.

143. Claim 9 calls for the apparatus of claim 5, further including electronic means for preventing the counting of particles not travelling perpendicular to the radioactive object. CX 4.

144. Bram suggests the use of two alternative systems for obtaining position-sensitive information in this proportional counters. Borkowski, Tr. 697. In one variation, he uses the high-resistance anode wire and rise-time measurement of the Borkowski and Kopp '377 patent (RX 1). CX 4, col. 4, lines 29-42. In the other, he uses a modification of the delay line method of Kaplan et al. (CX 1). CX 4, Fig. 6, col. 3, line 60 to col. 4, line 7.

G. Expert Opinion Respecting Bram Patent

145. In Dr. Rothberg's opinion, the Bram invention would have been obvious to one skilled in the art in 1974 because at that time conventional gas-flow proportional counters were already in use for chromatography, and the only step necessary to achieve the Bram combination was to replace the conventional anode wire with Borkowski and Kopp's position-sensitive high-resistance anode wire and electronics. Rothberg Dep., CX 134 at 79, 105.

146. Mr. Borkowski testified that there was nothing new or novel in the Bram patent and that the Bram patent was based upon prior art that was obvious to anybody skilled in the field. Borkowski, Tr. 689-90; Borkowski Dep., CX 132 at 76-77.

147. In Mr. Borkowski's opinion, there was nothing new or novel in the Bram patent because it was known in the prior art (1) that radioactive samples could be introduced into the sensitive volume of a detector chamber for measurement, and (2) that a conventional proportional counter could be transformed into a position-sensitive counter by replacing the anode wire of proportional counter with a resistive wire. Borkowski Dep., CX 132 at 86.

148. In Mr. Borkowski's opinion, anyone skilled in the art in 1974 would have known that there was no way to measure tritium through a window counter; in order to measure tritium, you had to put it inside the counter. Borkowski Dep., CX 132 at 58.

149. It was well known in 1974 that if one was interested in measuring low energy alpha or beta particles that it was best to put the radioactively emitting sample inside the counting chamber. Shulman Dep., RX 52 at 46, 131, 133.

H. Application of Proportional Counters to Chromatography

150. The 1969 patent issued to Borkowski and Kopp for a "Position-Sensitive Radiation Detector" (RX 1) suggests the applicability of position sensitive electronics to the measurement of low energy ionizing particles. Borkowski and Kopp disclose in their patent that "it is an object of this invention to provide a position-sensitive detector which is more sensitive to low energy ionizing particles." (RX 1, col. 2 lines 26-28) (emphasis added). They further explain that their "position-sensitive gas-filled detector . . . is more sensitive to low energy ionizing particles and has improved spatial resolution . . . ." RX 1, col. 3, lines 5-9.

151. The 1972 IEEE Transactions paper by Borkowski and Kopp entitled "Proportional Counter Photon Camera" (RX 40) discloses the applicability of this type of two-dimensional proportional counter to chromatography. In the introduction, it is stated: "Obviously, the camera can be adapted to detect and image other types of ionizing radiation, as, for example, electrons in chromatography experiments or neutrons in neutron diffraction experiments." RX 40 at 1; Kopp, Tr. 640.

152. Reference in the 1972 IEEE Transactions paper (RX 40) to the obvious applicability of Borkowski and Kopp's two-dimensional photon camera to measuring radioactivity on a chromatogram was based upon Borkowski and Kopp's prior experiment with a simulated ^{14}C chromatographic plate placed inside the experimental detector of RPX 10. Borkowski, Tr. 672-73; Kopp, Tr. 640-41.

153. Borkowski and Kopp, in their 1970 IEEE article entitled "Some Applications and Properties of One- and Two-Dimensional Position-Sensitive Proportional Counters," (RX 39) explain that "[t]hese position-sensitive

detectors are well suited for application in the life sciences for the localization of radioactive tracers in medical studies or in . . . two-dimensional chromatography. . ." RX 39 at 340.

154. Both the 1970 IEEE Transactions paper (RX 39) and the 1972 IEEE Transactions paper (RX 40) by Borkowski and Kopp were presented at the Nuclear Science Symposia (one in Washington, D.C., the other in San Francisco), and were published in the IEEE Transactions series of Nuclear Science. RX 39; RX 40; Kopp, Tr. 638.

155. When Dr. Rothberg first agreed to be an expert for respondents in this case, he assumed the role of "devil's advocate" and sought to understand what was patentable and unobvious about the Bram patent. Rothberg, Tr. 446-47.

156. Initially, Dr. Rothberg thought that the unobvious part of Bram had to do with applying a windowless gas-flow counter to a chromatogram. But, upon looking into it further, Dr. Rothberg discovered that there was substantial prior art concerning the application of windowless counters to chromatograms. Moreover, there were prior art examples of the use of gas-flow counters of the same general geometry as those in issue in this investigation. Accordingly, Dr. Rothberg reached the conclusion that there was nothing inventive about the Bram patent. Rothberg, Tr. 447-49; Rothberg Dep., CX 134 at 77-80.

157. The things that Dr. Rothberg could think of as potential problems in applying position-sensitive radiation detection to chromatography -- such as the build up of electric fields at the surface of the chromatogram

and getting the beta particles to enter the counter -- were shown in the prior art either not to be problems or to have been problems that were resolved. Rothberg, Tr. 448-49, 492; Rothberg Dep., CX 134 at 106.

158. Many concerns in radiochromatography, such as those relating to resolution and counting efficiency, are common to other kinds of radiation detection. Rothberg, Tr. 455.

159. Problems with electrostatic charge build-up that could arise from placing a dielectric sample plate inside a detector chamber would be no different for position-sensitive proportional counting than for conventional proportional counting. Polic Dep., CX 133 at 68.

160. Dr. Rothberg testified that, in his opinion, it would have been obvious to one skilled in the art of radiation detection in 1974 to try using a windowless position-sensitive proportional counter for obtaining position-sensitive information from a radiochromatogram. It would have been obvious to replace the ordinary proportional counters -- that were being used to analyze chromatograms -- with position-sensitive ones. Rothberg, Tr. 448, 456-59; Rothberg Dep., CX 134 at 105.

161. Dr. Shulman testified that windowless mechanical scanners are the same as imaging radiochromatogram analyzers in the sense that the radioactive sample in both types of devices is inside the sensitive gas volume of the chamber. Shulman, Tr. 141.

162. In a properly functioning position-sensitive proportional counter, once a single ion pair is produced, the probability is extremely high that the electron produced by that single ion pair will be detected through the process of gas multiplication. It does not matter what caused this ion

pair, whether it is an alpha particle, a beta particle, an X-ray, or a gamma ray; once you get the ion pair it will be detected. Shulman, Tr. 268-70.

163. The counting efficiencies disclosed by Berthold for ^{3}H and ^{14}C in his 1965 article on gas-flow proportional counters (RX 27) are as good or better than the counting efficiencies achieved in the current Bioscan BID 200. Shulman Tr. 363-64; RX 27 at 305-06.

I. <u>Conversion to Position Sensing Was Obvious</u>

164. The conventional proportional counter disclosed in the Borkowski and Fairstein '925 patent (RX 3) can be converted into a position-sensitive proportional counter by making use of the high-resistance wire disclosed in the Borkowski and Kopp '377 patent (RX 1). Shulman Dep., RX 52 at 71-72.

165. RPX 9 illustrates that you can take a high-resistance wire, as described in the '377 patent to Borkowski and Kopp (RX 1), and put it into a detector such as that of Figure 1 of the '925 patent to Borkowski and Fairstein (RX 3), thereby transforming the detector of RX 3 into a position-sensitive detector. Polic, Tr. 589-90.

166. The conventional proportional counter of the Borkowski and Fairstein '925 patent (RX 3), which is suitable for measuring ^{3}H or ^{14}C, can be converted into a position-sensitive proportional counter by substituting the high-resistance anode wire of the Borkowski and Kopp '377 patent (RX 1). Polic, Tr. 523-24; RPX 9.

167. Replacing the anode wire of Schulze and Wenzel (RX 17) with the high-resistance anode wire and appropriate electronics of the Borkowski and Kopp '377 patent (RX 1) would yield a position-sensitive proportional counter. Rothberg, Tr. 419.

168. The gas-flow proportional counter described in a 1962 article by Schulze and Wenzel (RX 17) could be converted into a position-sensing counter by replacing the anode wire of the Schulze and Wenzel counter with a high resistance anode wire as described in the 1969 Borkowski and Kopp '377 patent (RX 1). Shulman Dep., RX 52 at 83-84.

169. The two-dimensional thin-layer chromatogram scanner shown in the 1967 article by Berthold and Wenzel (RX 32) can be converted into a position-sensitive proportional counter by substituting the conductive tungsten anode with a highly-resistive anode and appropriate electronics, as disclosed in the Borkowski and Kopp '377 patent (RX 1). Borkowski, Tr. 683.

170. The gas-flow, radiochromatogram proportional scanner described in a 1965 article by Berthold (RX 27) could be converted by replacing the anode wire of the Berthold device with a high resistance anode wire as described in the 1969 Borkowski and Kopp '377 patent (RX 1). In essence, that is what has been developed and designed and sold to the market as radiochromatogram analyzers by the parties. Shulman Dep., RX 52 at 111; Shulman, Tr. 255-57.

171. The windowless, non-position-sensitive proportional counter of the '831 Kimmel patent (RX 2) can be converted into a position-sensitive proportional counter by substituting the high-resistance anode wire of the Borkowski and Kopp '377 patent (RX 1). Polic, Tr. 524.

172. In Dr. Shulman opinion, if one were to take the anode wire out of the Kimmel detector (RX 2) and replace it with a high resistance wire and electronics of the Borkowski and Kopp '377 patent (RX 1), one would have a position-sensitive proportional counter capable of measuring tritium on a thin layer chromatogram. Shulman, Tr. 262.

173. The primary difference between the non-position-sensitive system of the Packard Model 7201 (RX 42) and the position-sensitive proportional counter described in the '377 patent to Borkowski and Kopp (RX 1) is that the Packard system uses a very conductive anode wire whereas the system disclosed in the '377 patent uses a resistive wire. Polic, Tr. 513.

174. In Mr. Polic's opinion, there is no practical reason why Borkowski's anode wire and electronics of the '377 patent (RX 1) would not be compatible with the Packard Model 7201 detector (RX 42). Polic, Tr. 513-14.

J. Pertinent Art Not Before Patent Office

175. Dr. Rothberg testified that the most important prior art was not considered by the Patent Office during the prosecution of the Bram patent. Rothberg, Tr. 480-81.

175a. One category of prior art not considered by the Patent Office related to windowless gas-flow proportional counters applied to chromatography. CX 4, face page.

176. Dr. Rothberg testified that the prior art relating to placement of ^{14}C and ^{3}H inside the chamber of a conventional proportional counter was more pertinent than the "more or less peripheral" references that were before the Patent Office. Rothberg, Tr. 487-90.

177. Various prior art references disclosing the placement of a radioactive sample inside of detection chamber -- such as the Borkowski and Fairstein '925 patent (RX 3) -- were more relevant to the Bram patent than the Pocock, Lovelock and Dimick patents (CX 1) considered by the Patent Office. Polic, Tr. 567-74.

178. In Mr. Polic's opinion, the '831 Kimmel patent (RX 2) and the two Berthold articles (RX 27 and RX 32) are pertinent prior art not considered by the Patent Office. Polic, Tr. 573.

179. In Mr. Polic's opinion, the 1973 article by Kaplan et al. considered by the Patent Office was pertinent prior art. However, Mr. Polic believes that the patent examiner ignored pertinent discussions of pulse-height analysis and collimators found in the Kaplan article. Polic, Tr. 571.

180. The 1973 article by Prydz, considered by the Patent Office during the reexamination of the Bram patent (CX 2), does not discuss the use of windowless proportional counters for radiochromatogram scanners. All references by Prydz to windowless scanners are to Geiger-Muller counters. Prydz, CX 2 at 16-19; Shulman, Tr. 331-32.

K. Level of Skill in 1974

181. The field of radiation detector design in the early 1970s was driven by persons with training in physics and, in particular, high energy physics. Shulman, Dep., RX 52 at 269-70.

182. Mr. Polic was personally involved in the development of windowless, gas-flow radiochromatogram scanners at Packard prior to 1974. Polic, Tr. 510-11; RX 42.

183. Prior to 1974, Dr. Rothberg had first-hand experience in designing a gas-flow proportional counter with the source of electrons located inside the detector chamber. Rothberg, Tr. 491; Rothberg Dep., CX 134 at 7.

184. Dr. Shulman has training in chemistry and physics. CX 130. During his employment at the Naval Research Laboratory ("NRL") from 1970 to 1979, his work mainly involved developing instrumentation and detection methods for space applications of X-rays and gamma rays. Shulman, Tr. 95-96, 99.

185. Prior to beginning his work on a prototype position sensitive detector for chromatograms in mid-1975, Dr. Shulman had no background in biochemistry or chromatography. He learned the techniques and what was available in the marketplace and in the research lab at the time. Shulman, Tr. 98.

186. A person of ordinary skill in radiation detector design in 1974 would have a general familiarity with such journals as Nuclear Instruments and Methods, The Review of Scientific Instruments, and IEEE Transactions on Nuclear Science. Shulman Dep., RX 52 at 182-83, 251-52; Rothberg Dep., CX 134 at 88-89.

187. The Basic Measurement Science Group at ORNL was involved in trying to discover new methods of measurement. The Group never designed specific counters for specific applications. The mission of the Group was to conduct basic research open to anybody who wanted to see it. Often, after Borkowski and Kopp resented a paper at a conference, many visitors would come through the Group's laboratories at ORNL to look at the detector devices and ask questions. Kopp Dep., RX 56 at 20, 59; Kopp, Tr. 655.

188. Mr. Kopp's work in the Basic Measurement Science Group at ORNL mainly involved the development of position-sensitive proportional counters. Kopp Dep., RX 56 at 8-9.

189. Mr. Kopp testified that there is no other way to measure low energy particles than to put the sample inside the counting gas of the detector chamber. Whenever he and his co-workers measured low energy charged particles, they placed them inside the detector chamber. Kopp, Tr. 624, 632.

190. The April 1971 Program and Budget Proposal of Mr. Borkowski's division at ORNL contains the following statements under a heading entitled "Expected Results in FY 1972:"

> Development of two-dimensional position-sensitive detectors will be continued. The detector for determining the localization of radioactive tracers in the human body will be field tested. One- and two-dimensional detectors will be built to study the localization of ^{14}C in paper chromatographs. Methods for collimation and focusing of electrons will be developed.
>
> Investigation of the effects of externally applied magnetic fields on the spatial resolution of uncollimated beta particles in a position-sensitive detector will continue. Other one- and two-dimensional detectors will be built for localization of ^{14}C and ^{3}H.

Mr. Kopp testified that he and his co-workers continued the development of two-dimensional position sensitive proportional detectors, but they did no further work with chromatography or detection of ^{14}C or ^{3}H until 1981. RX 38A at 4; Kopp, Tr. 651-52.

190a. In the Oak Ridge National Laboratory Annual Report for the period ending September 1, 1971, and distributed throughout the world, Borkowski and Kopp indicated that their "main goal was to design two-dimensional position-sensitive detectors for application in the life sciences and for detection and localization of radioactive traces in the human body and in chromatographic samples." To that end they built a 100-wire counter and checked its resolution with collimated ^{14}C beta particles, Po-210 alpha particles and 5 keV X-rays (RX 41). In 1974, Borkowski and Kopp received U.S. Patent 3, 786,270 (RX 7) for their multiwire proportional counter radiation camera whose operation had been discussed in RX 40. Kopp Dep., RX 56 at 19.

1. Experimental detector at ORNL.

191. RPX 10 is a principal drawing of an experimental two-dimensional position-sensitive proportional counter built and used by Borkowski and Kopp at ORNL prior to 1974. Kopp, Tr. 623, 627; Kopp Dep., RX 56 at 13-17.

192. Mr. Kopp and co-workers at ORNL used the experimental detector of RPX 10 to measure radioactive samples placed in three different locations with respect to the detector chamber. For low energy particles, the source was placed inside the detector chamber. The detector could also be used with a source placed outside and measured through a thin window or with the source outside but measured through a hole in the window. Kopp, Tr. 624.

193. In May 1970, using the experimental detector of RPX 10, Mr. Kopp and co-workers performed position sensitive measurements of ^{14}C spots on a simulated chromatographic plate. In order to perform these measurements, the plate was placed inside the detector chamber. Kopp, Tr. 627, 635; Kopp Dep., RX 56 at 13-17.

194. In the May 1970 experiment with a simulated chromatographic plate containing ^{14}C, the experiment detector of RPX 10 was filled with an argon-methane gas mixture and the ^{14}C sample plate was placed inside the detector chamber, face-down towards the array of anode wires, with no window interposed. Kopp, Tr. 632-34.

195. The two-dimensional image resulting fro the May 1970 experiment involving ^{14}C was displayed in real time on a storage scope attached to the experimental detector and printed out from a Techtronics reader connected to the storage scope. Kopp, Tr. 636.

196. The spatial resolution for a collimated point source of ^{14}C obtainable in the experimental counter of RPX 10 was on the order 2 millimeters. Kopp Dep., RX 56 at 65-66.

2. Collimated Carbon-14 experiments.

197. An experiment by Borkowski and Kopp at ORNL in 1971 involved the introduction of collimated alpha and beta sources, including ^{14}C, into the chamber of a two-dimensional proportional counter through a hole in the chamber membrane. The collimated samples were introduced at various angles and the resulting positional information was then used for calibrating the spatial resolution of the detector. Kopp, Tr. 642-43; RX 41.

198. The Annual Progress Report from the Instrumentation and Controls Division of ORNL describes the 1971 experiment of Borkowski and Kopp using collimated ^{14}C samples. This Annual Progress Report is circulated to research centers all over the world. At the back of the Annual Progress Report, there is a distribution list showing distribution to 303 individuals and institutions. The Annual Progress Report reported to the scientific community on the work of the Instrumentation and Controls Division at ORNL. RX 41; Kopp, Tr. 642-44.

199. The 1971 experiment by Borkowski and Kopp using a collimated ^{14}C source for calibration purposes was conducted in a detector of the type described in Borkowski and Kopp's 1972 IEEE Transactions paper (RX 40). Kopp Dep., RX 56 at 25.

200. One skilled in the art would know that if you could measure a point source of ^{14}C and determine its position inside of the sensitive gas volume of a counter, you could count the same ^{14}C on a chromatographic plate or paper strip. Borkowski, Tr. 695.

3. Energy discrimination experiments.

201. Mr. Kopp and co-workers conducted a number of experiments in the 1970-1973 time period using pulse-height discrimination ("energy discrimination") to improve spatial resolution in the detection of charged particles. Kopp, Tr. 630-31; Rothberg, Tr. 443.

202. Mr. Kopp performed certain experiments in 1971 using collimated sources of ^{14}C electrons to determine whether energy discrimination could eliminate those beta particles that had an incidence of angle greater or less than the perpendicular. It was established that this could be done by simple energy discrimination since the larger pulses recorded on the detector wire were the result of particles traveling at an oblique angle to the wire. The smallest pulses were those close to perpendicular. By eliminating the large pulses, Kopp and co-workers were able to reject the angular-generated pulses. Elimination of these angular-generated pulse improved spatial resolution. Kopp, Tr. 647-48; Kopp Dep., RX 56 at 37-38; RX 38 at 3.

203. In a series of experiments with ^{14}C at ORNL, researchers in Mr. Borkowski's division used a one-dimensional counter with a hole punched in the window to measure the effect of varying magnetic fields on the spatial resolution of a point source of ^{14}C. These experiments, conducted in 1971 and reported to the Atomic Energy Commission in an ORNL Program and Budget

Proposal (RX 38), demonstrated that the spatial resolution of the ^{14}C point source improved as the magnetic field increased. Pulse-height discrimination was used to further improve the spatial resolution of the ^{14}C sample. Kopp, Tr. 630-31, 644-46; RX 38 at 3.

204. The ^{14}C proportional counter experiment described in the 1971 ORNL Program and Budget Proposal (RX 38), "energy discrimination" was used to improve spatial resolution of the ^{14}C point source in the proportional counter. Borkowski, Tr. 677; RX 38 at 3.

205. Mr. Borkowski was in agreement with Mr. Kopp's testimony regarding the ^{14}C proportional counter experiments conducted at ORNL in the early 1970s. Borkowski, Tr. 673.

L. Secondary Considerations

1. Dr. Shulman's contemporaneous invention.

206. Dr. Shulman had no experience in chromatography prior to the Spring or Summer of 1975, when he and a personal friend, Dr. Michael Lieberman, discussed the problems Dr. Lieberman was encountering in measuring radioactivity on thin layer chromatograms. Dr. Lieberman was using traditional liquid scintillation counting techniques. Shulman, Tr. 95-97.

206a. Since about the spring or summer of 1975, Dr. Shulman has been involved with the development of detectors for chromatography. From about 1975 to 1980, he and others collaborated to develop Bioscan's current commercial imaging chromatogram analyzer. Shulman, Tr. 96.

207. During the initial discussion of chromatography with Dr. Lieberman, Dr. Shulman had the idea that it might be possible to use a position-sensitive proportional counter to analyze Dr. Lieberman's samples. Shulman, Tr. 98.

208. The first prototype radiochromatogram detector built by Dr. Shulman at Naval Research Laboratory ("NRL") in 1975 resulted from a collection of ideas from basically two places: first, Dr. Shulman was familiar with Borkowski and Kopp's work in imaging proportional counters at ORNL; second, Dr. Shulman was familiar with research of a colleague at NRL, Dr. Chet Opal, who had developed and built position-sensitive readout systems for ultra-violet detection, using microchannel plates. Dr. Shulman combined Borkowski and Kopp's idea of a resistive anode wire with the "charge division" readout system at NRL. Shulman, Tr. 100.

208a. In 1975, Shulman devoted a considerable part of the time he spent on his device to making a resistive anode wire. Shulman Dep., RX 52 at 179, 237; Shulman, Tr. 219. The electronics were assembled from equipment with a value of $50,000-$100,000 already present in the laboratory. Shulman, Tr. 116, 220; Shulman Dep., RX 52 at 243. The detector was made by milling rectangular brass or aluminum tubing and mounting the anode wire. Shulman, Tr. 218. The first detector was approximately one-half inch thick. Shulman, Tr. 106.

209. The first prototype position-sensitive proportional counter for radiochromatography designed by Dr. Shulman in 1975 used charge division electronics for determining the position of the radioactivity on the anode, because the electronics for this charge division system were available at NRL. Dr. Shulman designed his first detector and preamplifiers to be compatible with this system. Shulman, Tr. 288-89; CX 20 at 2185; CX 155.

209a. Either chromatographic plates were inverted and placed atop Shulman's detector or the detector was placed over the chromatographic plate; operation was windowless (Shulman, Tr. 221, 223) for ^3H counting though a version with a window was also constructed. Shulman, Tr. 102-03.

210. Dr. Shulman's first position-sensitive measurements of a chromatogram yielded moderately good resolution, although a number of problems were experienced in getting the detector to work reliably. Shulman, Tr. 102.

211. Dr. Shulman's principal concern in building his first detector for measuring radiochromatograms was in obtaining a good resistive anode wire. There were also problems with making the electronics work in the detector. Shulman, Tr. 218-19.

211a. Shulman realized that a thinner detector offered the prospect of improved performance and constructed one that was one-quarter inch thick (Shulman, Tr. 106) between March 20, 1977 and March 23, 1977 (Shulman, Tr. 111).

211b. In 1978, Shulman initiated construction of a fully enclosed unit which was intended to completely contain a sample and several detector wires to permit multiple track analysis. Shulman, Tr. 118; Shulman Dep., RX 52 at 25-26, 77. The enclosed unit had gasketing and an over pressure relief valve. Shulman, Tr. 587-89.

212. In the first two months of operations, Dr. Shulman operated his prototype chromatogram detector in both a window mode and a windowless mode. Shulman, Tr. 102-03; CX 20 at 2180-83.

213. The early prototype detectors built by Dr. Shulman at NRL, such as CPX 4, were of very simple construction but were connected to very

expensive electronics for measuring and displaying the position of the radioactivity. CPX 4 was connected to a multi-channel analyzer that at the time probably cost $25,000 or $30,000, and to a Digital Equipment Computer that probably cost $15,000 or $20,000. Shulman, Tr. 116.

214. In 1975 when Dr. Shulman began designing position-sensitive proportional counters for radiochromatograms, he was aware from his other work on proportional counters at NRL of the gas-flow and gas-mixture requirements for building a proportional counter. Shulman, Tr. 287-88.

215. In trying to improve the resolution of his early prototype detectors, Dr. Shulman raised the voltage on the anode wire because "that's what you do with proportional counters." Shulman, Tr. 304.

216. When Dr. Shulman designed and built his first detectors for radiochromatography, he was not aware of the various papers that were available in the prior art on the detection of ^{3}H and ^{14}C from chromatographic plates. Shulman, Tr. 296.

217. To the extent that Dr. Shulman encountered problems with designing his first detectors for radiochromatography, he did not consult prior art publications, such as those by Berthold, which discuss the problems of radiochromatography detection. Dr. Shulman was unaware of that chromatography literature at the time. Shulman, Tr. 286.

217a. In 1979, Shulman decided to commercialize his device. He engaged a patent attorney with the object of obtaining patent protection. The Bram patent was discovered and a personal license to Shulman was negotiated. Shulman, Tr. 113-14. Shulman incorporated Bioscan in 1980 (Greenblatt Dep., CX 135 at 75) and transferred the Bram patent license to Bioscan, Inc. Shulman, Tr. 114.

217b. In August 1980, Shulman sold his fully enclosed unit to an investigator at the National Institutes of Health. CX 24.

217c. Shulman abandoned his fully enclosed unit as being unsaleable Greenblatt Dep., CX 135 at 111-12), overly complex and impractical and reverted to his original Naval Research Laboratory concept. Shulman Dep., RX 52 at 26-27.

2. Technical Assistance to Numelec

218. Dr. Jean Irunberry testified as a fact witness with respect to efforts to commercialize the position-sensitive detector built by Stanley Bram at Institut Pasteur. Irunberry, Tr. 55-92.

219. Dr. Irunberry never saw the position-sensitive detector built by Bram at Institut Pasteur and had no knowledge of the technical and design details of that device. Irunberry, Tr. 81-82.

219a. In 1974, Institut Pasteur attempted to license the French Bram patent to Intertechnique (Irunberry, Tr. 59), France's largest nuclear instrument company with more than 1200 employees (Irunberry, Tr. 68-69) and at that time the world's largest producer of multichannel analyzers (Irunberry, Tr. 69). Intertechnique was not interested in taking a license (Irunberry, Tr. 59). Several other companies were contacted but none of them took a license under the patent (Irunberry, Tr. 59).

220. In April 1976, when the technical assistance agreement between Institut Pasteur and Numelec was signed, Numelec had a prototype position-sensitive radiation detector that was not functioning very well. Irunberry, Tr. 61, 63, 88-89f; CX 16.

220a. The agreement between Institut Pasteur and Numelec was for technical assistance. Irunberry, Tr. 61; Shulman Dep., RX 52 at 200.

221. Dr. Irunberry had no knowledge as to the technical details of Stanley Bram's involvement with Numelec in developing the "Chromolec" detector. Irunberry, Tr. 87.

222. Numelec sold 10-15 position-sensitive chromatogram analyzers in the years of 1976-77 for which they paid Institut Pasteur technical assistance fees of 20,000-30,000 French francs (Irunberry, Tr. 77). By 1980, Numelec no longer sold PSPCs and no further payments were made. Irunberry, Tr. 78.

223. Dr. Irunberry does not believe that any Chromolec detectors were sold in 1981 and 1982. Irunberry, Tr. 78, 91.

3. Packard rejected position sensitive detection.

224. In the early 1970's, Packard considered the development of a position-sensitive proportional counter for radiochromatograms but rejected the idea because of the expense of the electronics required for such a device. The sales cost of a position-sensitive device would have been about $40,000. In contrast, Packard was selling its Model 7201 scanner for $5,000 to $7,000. Polic, Tr. 517-19.

225. In about 1976, Packard's Advance Development Group, led by Dr. Leroy Everett, evaluated a position-sensitive proportional counter manufactured by Numelec. A couple of test samples were analyzed and some cost estimates were made. However, Packard did not pursue the development or marketing of such a device at that time because the test results from the Numelec device were relatively poor and the cost of the device was very high. Polic, Tr. 519, 566, 579-80.

226. After execution of the April 1976 technical assistance agreement between Numelec and Institut Pasteur, the Numelec position-sensitive detector -- designated "Chromolec" -- was demonstrated to Packard, but no contract resulted because the Chromolec did not give very good results. As part of the Packard evaluation, a technician for Packard operated the Chromolec prototype at Institut Pasteur in 1976. Irunberry, Tr. 64-65, 79, 87-88.

227. In the 1970-1976 time period, Packard had the majority of the market in conventional radiochromatogram scanners. Polic, Tr. 519-21.

228. Packard has always designed instruments with state-of-the-art electronics. For example, Packard was the first to use transistors and the first to use integrated circuits in the United States. Polic, Tr. 439; Polic Dep., CX 133 at 81.

229. The cost of the electronics for position-sensitive proportional counters in 1974 was such that it was not commercially feasible to market the devices at that time. In 1974, a multi-channel analyzer cost about $15,000 to $20,000. Similarly in 1974, a PDP computer cost about $15,000 to $20,000. Polic, Tr. 564-66.

230. In the past five years, with the advent of personal computers offering large memory storage at very low prices, the marketing of position-sensitive proportional counters has become more commercially feasible. Polic, Tr. 667.

230a. Shulman licensed the '057 patent in December 1979; this license and Bioscan's sub-license to Berthold Instruments are the only licenses granted under the Bram patents. CX 7.

M. Enablement

1. Claim 5.

231. Bram provides two principal embodiments for his invention in col. 6, lines 46-57, and in col. 6, lines 57-60. CX 4.

232. In the embodiment described in col. 6, lines 46-57, three sides of the counting chamber are constructed of base 20 and frame 22, "with both made of non-conducting material." The fourth side, window 30, "is relatively thick and can be made of a conductor" or of plastic with a conductive coating "on its inside surface in which case it functions as the cathode." CX 4.

233. Figure 2 of the Bram patent shows that in the embodiment of col. 6, lines 46-57 the sample is intended to be interposed between the anode and cathode on internal support 38. CX 4; Polic, Tr. 503.

234. Interposing a dielectric such as a chromatographic plate between an anode and cathode within the counting chamber causes potential problems in counting. If the walls of the chamber of the chromatogram analyzer are made of insulating material, rather than conducting material, charge build-up will result. If the charge build-up is great enough, it will completely distort the electric field inside the detector and alter the counting characteristics, which will cause the counter to cease to function as a stable counting device. Shulman, Tr. 384; Rothberg, Tr. 449.

235. In position-sensitive detectors disclosed by the Bram patent, there is the potential for a problem from charge build-up of the positive ions returning to any surface which is not conducting. Because of potential charge

build-up problems, the inside walls of chromatogram analyzer detector chambers are made to be conductors which are held at ground potential. Shulman, Tr. 384.

236. The embodiment described in col. 6, lines 57-60 states "Alternatively, frame 20 can be made of metal or have a metal coating to function as the cathode instead of using the window coating. CX 4.

237. A device as described in col. 6, lines 57-60, with three non-conductive sides, would not be a suitable counter for position sensing because a charge would quickly build-up on the side walls, which are insulators. This charge build-up would distort the field so that the detector could no longer count. Polic, Tr. 503.

238. A variation of the '057 patent, column 8, lines 12-33, describes a closed counting chamber with the sample positioned external to the chamber and with provision for the radiations to be measured to penetrate a window transparent to said radiations. No details of construction are given and no claims touch on this device. Shulman, Tr. 212.

239. Bram provides no dimensions for any part of his device in the patent specifications or claims. Shulman, Tr. 185, 206.

240. In his patent, Bram makes reference to particles impinging upon the detector wire, but makes no reference to secondary electrons. Shulman, Tr. 250.

241. Careful attention to dimensions is important in constructing a working chromatogram analyzer of the Bram type. Shulman, Tr. 171-72.

242. Throughout the Bram patent is is maintained that it is the primary particles produced by radioactive decay, rather than the secondary electrons, that are being counted. References in the patent showing particle counting include: (1) Such pressurization is preferred in order to increase resolution of the detector since those errant particles with a high angle of incidence into the detector . . . CX 4, col. 2, line 38; (2) Electrical circuitry is then utilized to determine the position along the wire at which a particle is sensed. CX 4, col. 4, line 40; (3) Also errant particles will reach the collector wire without having had the opportunity . . . CX 4, col. 7, line 23.

243. One skilled in the art reading the Bram patent would reach the implication that Bram is measuring the primary particle and not the secondary electrons that are produced by ionizing the gas. Rothberg, Tr. 400.

244. Teaching of the principle of gas multiplication in proportional counting was well-known in 1974 and goes back more than 50 years. Rothberg, Tr. 450.

245. Even today, there does not exist an amplifier with a low enough noise level capable of detecting a single electron in a proportional counter. However, through the process of gas multiplication inherent in a proportional counter, the energy emitted by one electron, resulting in a single ion pair, is multiplied approximately 10,000 times. It is this larger pulse that is detected on the anode wire of a proportional counter. Borkowski, Tr. 681.

246. It takes several hundred electrons, at least, to be detected by modern electronics. Shulman, Tr. 270.

247. In reality, a single particle cannot be detected in either the Bram device or those at issue today, because of two reasons: (1) the electronics do not exist to detect a single particle or electron; and (2) less than a hundredth of a percent of the particles actually strike the detector wire. Shulman, Tr. 248-49; Rothberg, Tr. 400; Borkowski, Tr. 681; Polic, Tr. 509.

248. INTENTIONALLY UNUSED.

249. In a position-sensitive detector such as in the Bram patent and the devices at issue, the typical voltage range of operation is 1,200 to 1,700 volts. Shulman, Tr. 324.

2. Claim 9.

250. Claim 9 of the Bram patent reads as follows:

> The apparatus of claim 5, further including means connected to said counting means for preventing the counting of those particles not traveling at an angle substantially perpendicular to said object. CX 4.

251. If Bram's pulse height discrimination system of claim 9 is directed at actually discriminating between particles based upon the distance they have travelled, it is inoperable because there would be no difference between the energy of any particles, and no electronic system for establishing angularity would be feasible. Borkowski, Tr. 681; Rothberg, Tr. 407; CX 134, Dep. 118; Polic, Tr. 542; (emphasis added).

252. In his description of circuit F of the pulse height discrimination system, Bram describes it as "comprised of a preamplifier 15 operably connected to wire 6 and to a linear amplifier 17." CX 4, col. 7, lines 57-59.

253. Figure 1 shows the circuitry for the pulse-height discrimination system of claim 9 connected to the cathode, but in the specification, Bram describes the circuitry as operably connected to the anode. CX 4, col. 7, lines 58-56, Fig. 1 (emphasis added).

254. Nowhere in the Bram patent specifications, drawings or claims is the term "operably connected" as pertaining to circuit F, defined or described. CX 4; Rothberg, Tr. 412.

255. Bram claim 9 is directed to the elimination of counts derived from primary particles which leave the sample at angles substantially deviating from the perpendicular. CX 4, col. 7, lines 38-47.

256. In a proportional counter, a pulse discrimination system can discriminate against particles which are emitted away from the vertical into the detector, because particles which are emitted on a slant angle will have a longer path through the gas than particles which go straight to the detector wire. Since a larger pulse amplitude is produced by those particles travelling at an angle from the sample, the discarding of those larger pulses will improve the resolution of the measurement in the detector. Shulman, Tr. 153; Borkowski, Tr. 677; Borkowski Dep., CX 132 at 133.

257. One skilled in the art would conclude that the pulse height system of Bram as described in claim 9 of his patent actually rejects those small pulses he would like to keep and thus is inoperative based upon the following descriptions of the claim 9 system in the specifications (Rothberg, Tr. 412):

> Selection circuit F is used to prevent the display of data from particles that are errant beyond a maximum limit. It does so by sensing the pulse magnitude on the wire 5 caused by each particle. Since the magnitude is

> dependent on the distance travelled by the particle, should this distance exceed a maximum, i.e., the pulse magnitude is below a minimum, circuit F blocks the normal operation of converter B. CX 4, col. 7, lines 50-57.... Further improvement can be obtained by pressurizing the gas within the detector beyond atmospheric pressure and by eliminating pulses below a certain magnitude with electronic circuitry. CX 4, col. 9, lines 6-9.

258. Those skilled in the art explain Bram's rejection of the wrong pulses for the pulse height discrimination system of claim 9 as based upon his mistaken belief that he was measuring kinetic energy of particles reaching the wire, and that those particles would lose more energy the farther they travelled through the medium. Polic, Tr. 547-48; Rothberg, Tr. 400.

259. Respondents' expert witness, Mr. Borkowski, in describing his systems of pulse height discrimination, stated that only positive pulses, not negative pulses were rejected. Borkowski, Tr. 677.

260. There is no indication in the Bram patent that Bram is measuring negative pulses in the pulse height discrimination system of claim 9. CX 4.

261. Those skilled in the art, in the absence of an indication to the contrary, would interpret the Bram specification to mean that the circuitry for measurement of pulse heights is measuring absolute values, i.e., positive magnitudes, of those pulse heights. Rothberg, Tr. 427; Rothberg Dep., CX 134 at 72; Polic, Tr. 544.

IV. INFRINGEMENT

A. Direct Infringement of Claim 5

262. Claim 5 of the Bram patent reads as follows:

> 1. In an apparatus for determining the spatial distribution of the radioactivity in an object, the combination comprising a detector having a completely enclosed chambers containing a ionizable gas at least a portion of one wall of said chamber being removable, an elongated conductor extending longitudinally of and fixedly secured within said chamber, a support attached inside said chamber to said chamber walls in close proximity to said elongated conductor, said support being adapted to mount said object in close proximity and substantially in parallel to said elongated conductor, means operatively connected to said elongated conductor for determining the location along said elongated conductor of radioactive particles emitted by said object and reaching the proximity of said location, means connected to said determining means for counting the number of said particles at each one of a plurality of said locations, and a display device connected to the output of said counting means.

CX 4.

263. The Bioscan, RITA and Aloka chromatogram analyzers at issue determine spatial distribution of radioactivity in a sample by detection in one-dimension. Shulman, Tr. 356; CX 25; CX 35; CX 55.

264. The Bioscan, RITA and Aloka chromatogram analyzers utilize an elongated conductor extended longitudinally within the detector head. CX 25; CX 35; CX 55.

265. For purposes of determining infringement of claim 5 of the Bram patent, the chromatogram analyzers of Bioscan and respondents are identical. Rothberg, Tr. 407-09; Polic, Tr. 507; Polic Dep., CX 133 at 72.

1. <u>Completely enclosed chamber of Claim 5.</u>

266. In the Bioscan chromatogram analyzer the distance of the gap between the detector head and sample varies depending upon different gas flow rates through the detector. Shulman, Tr. 124.

267. Figure 2a of the Bram patent shows a tightly sealed chamber with part 44 forming a gasket to make a tight seal so that the chamber could hold pressure if the window 30 is made sufficiently strong. Shulman, Tr. 237.

268. Although Bram does not mention gas flow in the '057 patent, there are several places in the patent where he cites pressurization and sealed chambers: (1) The Bram patent specifications show that "the chamber is to be sealed with a strong material to enable pressurization of the chamber beyond atmospheric pressure." CX 4, col. 4, lines 38-40; (2) "Such pressurization is preferred in order to increase resolution." CX 4, col. 2, line 38; (3) "The detector chamber can be pressurized to much more than atmospheric pressure." CX 4, col. 6, lines 34-37; (4) "Further improvement can be obtained by pressurizing the gas." CX 4, col. 9, lines 6-9.

269. The RITA chromatogram analyzer detector head has a gas flow rate of approximately 1 liter per minute through a volume in the detector head of 20 cubic centimeters. Rapkin, Tr. 351.

270. The RITA chromatogram analyzer detector head does not form a seal with the sample during detection because the samples are made with a step so that gas will flood the area. Rapkin, Tr. 351.

271. The Bioscan and Aloka chromatogram analyzers are manufactured with spacers on the detector head so that a gap will exist between the collimator and sample equal to the thickness of those spacers. Shulman, Tr. 358; CX 58.

272. The Bioscan chromatogram analyzer detector head has a gas flow rate of approximately 1/2 liter per minute through its 20 cubic centimeter volume. Shulman, Tr. 372.

273. The Bioscan, RITA and Aloka chromatogram analyzers are not completely enclosed chambers because they are gas flow chromatogram analyzers. Rothberg, Tr. 408, 477.

274. One skilled in the art would interpret the "completely enclosed" chamber of claim 5 as being a closed or sealed box that would not allow gas to escape. Rothberg, Tr. 422; Polic, Tr. 499.

275. The French Bram Application No. 74.14453 which is submitted to the Patent Office on February 26, 1975 during the prosecution of the Bram patent in order to gain the French priority date of April 25, 1974, discloses a chamber which is hermetically sealed. CX 3 at 5; Polic, Tr. 500.

276. A sealed chamber is diametrically different from gas flow operation. Polic, Tr. 506.

277. The "commercial prototype" (CPX 3) of the Bioscan device that existed at the time that Bioscan took a license under the Bram patent was constructed such that it could be sealed and its pressure raised significantly above atmospheric, as indicated by gaskets, a pressure relief valve and a considerable number of screws holding the top of the chamber down. Polic. Tr. 528; CX 4, Fig. 2A.

278. The "commercial prototype" (CPX 3) of the Bioscan analyzer that existed at the time that Bioscan took a license under the Bram patent would be covered under claim 5. Polic, Tr. 529-30.

279. Bioscan sells two chromatogram analyzers under the model
C numbers System 200 and 400,
C . Shulman, Tr. 355.

280. In the Bioscan 200 and 400 model analyzers, the detector head has a slot in the bottom with a removable window. With the window removed, the detector is lowered to a measuring position over a sample mounted on a flat surface, the analyzer base plate. An ionizable gas is then introduced into the detector head and flows through the slot to reach the sample to be counted and then into the surrounding atmosphere through the gap between the detector and the sample plate formed by spacers attached to the detector head. CX 31; Shulman, Tr. 125-26, 357; Complaint at 16-17.

281. The Isomess RITA chromatogram analyzer has a chamber which is open at the bottom and has ports communicating with the surrounding atmosphere. The bottom region of the chamber is defined by a plate with a longitudinal slot running substantially the length and width of the chamber. The slot provides an opening in the bottom of the chamber through which ionizable gas continually flows to come in contact with the sample being counted before flowing into the surrounding atmosphere. CX 35, Rapkin, Tr. 349-50; Response to Complaint, Exh. A1.

282. In the Aloka Model RS analyzer, the detector head has a lengthwise slot which provides a chamber which is open at the bottom. For counting a sample plate is raised into position under the detector assembly. A gap between the detector and the sample is created by spacers of greater thickness than the sample plate. During analysis of the sample plate, an ionizable gas is continually introduced into the detector through the gas inlet and continually flows out of the slot in the base into the surrounding atmosphere through the gap between the detector and the sample plate. Reich, Tr. 609; CX 57, Response to Complaint, Exh. A1.

2. Removable wall and internal support of Claim 5.

283. In the Bioscan chromatogram analyzer, a sample is placed on an analyzer base plate external to the detector head for analysis. The bottom of the detector is then lowered over the sample and an ionizable gas flows from a slot in the detector to the sample while the radioactivity analysis is being performed. CX 31; Shulman, Tr. 125-26; Complaint at 16-17.

284. In the Isomess RITA analyzer, the support is outside the chamber, underneath the detector during analysis of the sample. An ionizable gas flows through a slot in the bottom wall of the detector head to the sample while radioactivity analysis is being performed. Shulman, Tr. 175; CX 35; Rapkin, Tr. 349-50; Response to Complaint, Exh. A1.

285. In the Aloka analyzer, the sample plate base is movably positioned exterior to the detector head. With a sample plate positioned on the sample plate base, the sample plate is raised into position under the detector and an ionizable gas flows from a slot in the detector above while analysis takes place. Shulman, Tr. 179; Reich, Tr. 609; CX 57; Response to Complaint, Exh. A1.

286. In the Isomess RITA analyzer, the detector lifts off of the sample support so it is the detector head which is being removed from the sample plate. Shulman, Tr. 175.

287. In the Aloka analyzer, an elevator system raises the sample up to the detector. Shulman, Tr. 179.

288. In the Bioscan chromatogram analyzers, the detector lifts off the sample support so it is the detector head which is lowered and removed from the sample plate in order for counting to be performed. Shulman, Tr. 363.

289. In the Bioscan and RITA chromatogram analyzers, the only mechanical connection between the plate which supports the sample and the detector head is an arm which is connected to the base and supports the detector head as it is lowered and raised from the sample. Shulman, Tr. 371; Rapkin, Tr. 350.

290. In the Aloka analyzer, the detector is stationary, and the sample table moves below it to position the sample for analysis. Reich, Tr. 609.

291. In figure 2a of the Bram patent, there are two walls represented which could be removed. One is the wall at the top, which is composed of parts 30, 32, and screws 46, the other is the wall at the bottom, which is part 20 and screws 43. CX 4; Polic Tr. 499.

292. The portion of the wall that is removable in the chamber as described in claim 5, is removable so that a sample can be put into it. Polic, Tr. 499-500.

293. A sample cannot act as the removable wall of the Bram claim 5 because the samples are not solid enough to contain a gas inside the chamber or to seal the chamber up. Polic, Tr. 500.

294. A paper chromatogram sample could not serve as the removable wall of claim 5 of Bram because it is porous to gases. Polic, Tr. 501.

295. The sample support of the Bioscan, RITA and Aloka analyzers is not the internal support of Bram's patent because the sample is external to the chamber and there is no support inside the chambers themselves. Polic, Tr. 504; Rothberg, Tr. 409.

296. None of the Bioscan, RITA and Aloka analyzers have a portion of one chamber wall that is removable, or a support inside said chamber as described by claim 5 of the Bram patent. Polic, Tr. 505; Rothberg, Tr. 407.

297. The Bioscan commercial prototype (CPX 3) had a removable wall and a sample holder mounted inside the wall of the chamber as described in claim 5 of Bram. Polic, Tr. 529.

B. <u>Direct Infringement of Claims 8 and 9</u>

298. Claim 8 of the Bram patent reads as follows:

> The apparatus of claim 5, further comprising a collimator placed between said object and said elongated conductor.

CX 4.

299. Claim 9 of the Bram patent reads as follows:

> The apparatus of claim 5, further including means connected to said counting means for preventing the counting of those particles not traveling at an angle substantially perpendicular to said object.

CX 4

300. Claim 8 of the Bram patent is dependent upon claim 5. CX 4.

301. Claim 9 of the Bram patent is dependent upon claim 5. CX 4.

302. The Bioscan, RITA, and Aloka chromatogram analyzers include a mechanical collimator as described in claim 8. Rothberg, Tr. 410; CX 31; CX 35; CX 57.

303. The Bioscan and RITA chromatogram analyzers have electronic counting means for discriminating pulses obtained from particles emitted from the sample which do not travel to the conductor in a straight path as described in claim 9 of the Bram patent. CX 31; CX 35.

304. The Aloka chromatogram analyzer does not have electronic counting means for discriminating pulses obtained from particles emitted from the sample which do not travel to the conductor in a straight path as described in claim 9 of the Bram patent. CX 57.

C. Infringement Under the Doctrine of Equivalents

305. During the original prosecution of the Bram patent, in rejecting claims 1, 2, 5-10 under 35 U.S.C. § 103, the examiner concluded that:

> The only difference between U.S. Patent No. 3,483,377 and [the] system claimed is the placing of the object within the chamber. B & C [U.S. Patent Nos. 3,008,051 and 3,176,135, issued to Pocock and Lovelock] show that it is old to place radioactive material within a chamber for testing and measuring. It is considered obvious to place objects within a sealed chamber for the same purpose as claimed. Furthermore, holder for such object within the chamber is a necessity . . . .

CX 1, Part II, Notification of Rejection(s) and/or Objection(s) at 2.

306. The following argument was made to overcome the examiner's rejection of claims 1, 2, 5-10 under 35 U.S.C. § 103 during the original prosecution of the Bram patent:

> The Examiner admits that a difference between the Borkowski and the claimed system is the placing of the measuring object within the chamber.

CX 1, Response to the Office Action, dated Jan. 7, 1986, at 7.

307. The following argument was made to overcome the examiner's rejection of claims 1, 2, 5-10 under 35 U.S.C. § 103 during the original prosecution of the Bram patent:

> It is therefore, obvious that none of these references taken individually or in combination teach the placement of the object to be analyzed within the chamber. The examiner's comment that it is old to place radioactive material within a chamber for testing and measuring is incorrect if the material referred to is the object to be analyzed.

CX 1, Response to Office Action, dated Jan. 7, 1986, at 8.

308. The following argument was made to overcome the examiner's rejection of claims 1, 2, 5-10 under 35 U.S.C. § 103 during the original prosecution of the Bram patent:

> In summation, applicant's invention rests, at least in part, on the fact that the object which is to be analyzed is placed within the chamber of applicant's position-sensitive radiation detector such that the spatial distribution of the radioactivity within the object can be determined, when the object admits (sic) only relatively low energy particles.

CX 1, Response to the Office Action, dated Jan. 7, 1986 at 9.

309. The patent specification of the Bram patent states:

> The present invention is related to a method and apparatus for determining the spatial distribution of radioactivity in an object, and more particularly to an arrangement for enclosing the object inside the detector.

CX 4, col. 1, lines 6-10.

310. The patent specification of the Bram patent states:

> Placing the radioactive object inside the detector eliminates the need for a window and permits such double labeled experiments.

CX 4, col. 3, lines 5-8.

311. The patent specification of the Bram patent states:

> In accordance with these objects, efficient counting of low energy particles and a determination of their spatial distribution with a high spatial resolution is enabled by placing the object inside the detector chamber.

CX 4, col. 4, lines 29-34.

312. The following argument was made to overcome the examiner's rejection of claims under 35 U.S.C. § 112 during the original prosecution of the Bram patent:

> "placement of a solid object within the chamber of a position-sensitive radiation detector" is an "important aspect" of the applicant's invention.

CX 1, Response to Office Action, dated Jan. 7, 1986 at 5.

313. The following argument was made to overcome the examiner's rejection of claims 5-10 and 12-15 under 35 U.S.C. § 112 during the original prosecution of the Bram patent:

> Claims 5-10 and 12-15 relate to the apparatus for determining the spatial distribution of the radioactivity in an object. Each of these claims define a chamber having a support attached inside the chamber to the chamber walls in close proximity to the elongated conductor, the support being adapted to mount the object in close proximity and substantially in parallel to the elongated conductor.
>
> It is believed that the above-mentioned limitations clearly define and distinctly claim the novel part of applicant's invention.

CX 1, Response to Office Action, dated Jan. 7, 1986 at 4 (emphasis added).

D. Inducement to Infringement

314. Respondent Aloka, Co., Ltd. ("Aloka") is a corporation organized under the laws of Japan with a place of business at 22-1 6 Chome, Mure, Mitakashi, Tokyo 181, Japan. CX 164, Stipulation 4.

315. Respondent ISOMESS Isotopenmessgerate GmbH ("ISOMESS") is a corporation organized under the laws of the Federal Republic of Germany with a place of business at Benzstr. 4, 7541 Straubenhardt, 1 Federal Republic of Germany. CX 164, Stipulation 6.

316. IN/US presently markets in the United States an imaging chromatogram analyzer manufactured abroad for sale into the United States by ISOMESS; the imported IN/US imaging chromatogram analyzer has been marketed in the United States since about January 1986, under the name Radioactivity Intelligent Thin-Layer Analyzer. CX 164, Stipulation 25.

317. Radiomatic markets in the United States an imaging chromatogram analyzer manufactured abroad by Aloka; the imported Radiomatic imaging chromatogram analyzer has been marketed in the United States since about April 1985, under the model designation Model RS Thin-Layer Chromatogram Scanner. CX 164, Stipulation 26.

E. Enforceability of the Bram Patent

318. During the original prosecution of the Bram patent, in rejecting claims 1, 2, 5-10 under 35 U.S.C. § 103, the examiner concluded that:

> The only difference between A [U.S. Patent No. 3,483,377] and [the] system claimed is the placing of the object within the chamber. B & C [U.S. Patent Nos. 3,008,051and 3,176,135, issued to Pocock and Lovelock] show that it is old to place radioactive material within a chamber for testing and measuring. It is considered obvious to place objects within a sealed chamber for the same purpose as claimed. Furthermore, holder for such object within the chamber is a necessity. . . .

CX 1, Part III, Notification of Rejection(s) and/or Objection(s) at 2.

319. In the applicant's May 4, 1976, response to the Examiner's rejection of January 7, 1976, the applicant's attorney argued that the asserted invention was novel because unlike prior art devices, the invention provided for placement of the object to be measured within the chamber:

> The examiner's comment that it is old to place radioactive material within a chamber for testing and measuring is incorrect if the material referred to is the object to be analyzed.

CX 1, Response to Office Action, dated Jan. 7, 1976 at 8.

320. INTENTIONALLY UNUSED.

321. Respondents' expert Mr. Borkowski testified that it was indeed old in the art to place a radioactive object within the chamber and that he had used this procedure in 1948, well before the Bram patent filing date. Borkowski, Tr. 674.

322. Neither deposition or live testimony of the patentee's attorney, Harold James, was introduced at trial.

323. During reexamination of the '057 patent, the following statement was made by Dr. Seth Shulman, "Numelec, a French Company, has been licensed under the French Patent. . ." CX 2, Affidavit of Dr. Shulman at 10.

324. Numelec entered into an agreement with technical assistance to Institut Pasteur which called for "royalty" payments to Institut Pasteur for each device developed under the agreement and sold by Numelec. CX 19.

325. Institut Pasteur paid a monthly salary directly to Bram as a result of the technical assistance agreement with Numelec. Irunberry, Tr. 74; CX 19.

326. Numelec paid royalties under the technical assistance agreement to Institut Pasteur for a period of two to four years. Irunberry, Tr. 77-78.

327. Neither deposition nor live testimony of the patentee's licensing attorney during the reissue proceeding was introduced at trial.

V. DOMESTIC INDUSTRY

328. Since 1980, Bioscan has been the sole domestic manufacturer of imaging chromatogram analyzers capable of sensing ^{3}H. CX 161C, at 4.

329. Beginning in FY 1983, Bioscan has been selling its System 200 imaging chromatogram analyzer. Its current price for a System 200 with
C computer ranges from $ for an Apple IIe equipped system to $ for a Hewlett-Packard 85B equipped system. CX 161C, Exh. 4.

330. In FY 1985, Bioscan introduced the System 500 CG. The System
C 500 CG
C
C . The System 500 CG retails for approximately
C $. CX 161C, Exhs. 4, 5.

331. In FY 1986, Bioscan began to sell the System 400-IIe for
C $16,600. The System 400-IIe
C
C (CX 161C, Exh. 4). The difference between a single disk drive and a dual disk drive is less than $250.00. CX 161C, at 5.

332. Bioscan currently offers three models of imaging chromatogram analyzers, the System 200, System 400, and System 500. CX 32-CX 34.

C 333. The basic Bioscan system includes
C
C
C . Further, optional equipment and accessories include
C
C . CX 32-CX 34, CX 107C.

334. Each Bioscan model of imaging chromatogram analyzer uses

C

C

C

C . CX 32-CX 34, CX 107C.

335. Bioscan's fiscal year ("FY") is from November 1 to October 31. CX 161C, at 3.

C 336. In FY 1983-1985, Bioscan's

C . CX 161C, at 4.

C 337. In FY 1983, Bioscan

C and sold units (CX 104C) for $ (CX 101C at 4).

338. In FY 1984, Bioscan sold imaging chromatograms analyzers

C and sold units (CX 104C) for $ (CX 100C at 4).

C 339. In FY 1985, Bioscan sold imaging chromatogram analyzers

C (CX 104C) for $ (CX 100C at 4).

C 340. In FY 1986, Bioscan sold imaging chromatogram analyzers

C (CX 104C) for $ out of $ in total sales (CX 99C at 3).

341. In Bioscan's FY 1984, Berthold, as a sublicensee of Bioscan,

C sold imaging chromatogram analyzers. CX 161C, Exh. 1.

342. In FY 1985, that is, October 1, 1984 to September 30, 1985,

C Berthold sold imaging chromatogram analyzers. CX 161C, Exh. 1.

343. In FY 1986, that is, October 1, 1985 to September 30, 1986,

C Berthold sold imaging chromatogram analyzers. CX 161C, Exh. 1.

344. Until the introduction of the Aloka Model RS TLC Scanner in April, 1985, Bioscan and Berthold, a Bioscan sublicensee under Bram, were the only domestic vendors of "imaging chromatogram analyzers." CX 13, CX 14C.

VI. EFFICIENT AND ECONOMIC OPERATION

345. Since 1980, Bioscan has continuously spent substantial sums

C . CX 159C, at 1.

346. Bioscan's offices and production facility are located at 4590 MacArthur Boulevard, N.W., Washington, D.C. 20007. CX 159C, at 1.

C 347. .

CX 159C, at 1.

348. Bioscan's production and diagnostic equipment is modern. CX 159C, at 1.

349. Bioscan's employees are highly skilled technicians and computer programmers. CX 159C, at 1.

C 350. Bioscan's facilities and staff are

C

C .

CX 159C, at 2.

351. Bioscan's method of manufacturing imaging chromatogram

C analyzers

C :

C

C

C

C

C

C

C
C
C
C
C
C
C
C
C
C
C
C

CX 159C, at 2-3.

C
352. After an imaging chromatogram analyzer is fully assembled

C
C
C
C
C
C

CX 159C, at 3.

353. Bioscan's approximate employment figures are as follows:

C
C
C
C

354. Bioscan's technical employees are highly skilled:

> Dr. Seth Shulman holds a Ph.D. in physics;
>
> Mr. Phillip Hurst, chief of operations, holds a masters degree in engineering with extensive experience in the instrumentation field;
>
> Mr. Seth Ornstein is the chief programmer with substantial expertise in software development;
>
> Dr. W. Neil Johnson is a digital engineering and software development consultant with a Ph.D. in physics;
>
> Mr. Gilbert Fritz is in charge of the electronic and analog circuitry and has substantial experience in the development of instruments for space flight.

CX 159C, at 3.

VII. INJURY

355. If "imaging chromatogram analyzers" is defined so as to include the quantitative analysis of soft beta radioactivity from tritium, the AMBIS Beta Scanning System is not an "imaging chromatogram analyzer." CX 128; SX 12.

356. Most of the potential customers for the imaging chromatogram analyzers sold by Bioscan, IN/US, and Radiomatic desire to measure soft beta radioactivity from ^{3}H, ^{14}C, or ^{32}P. CX 163C, at 2.

357. Today, the United States market for "imaging chromatogram analyzers" is divided among Bioscan, Berthold, and respondents IN/US and Radiomatic. CX 126C, CX 109C, CX 127C, CX 13, CX 14C.

358. Bioscan, with its imaging chromatogram analyzers, Radiomatic, with its Model RS TLC scanner imaging chromatogram analyzer, and IN/US with the RITA imaging chromatogram analyzer, have all directly competed and continue to compete for sales to some of the same potential customers in the United States. CX 162C, at 3; CX 163C, at 2

C 359. At the following locations, Bioscan

C

C

C

C

C

C

C

CX 160C, at 3.

A. IN/US

360. RITA and the Bioscan imaging chromatogram analyzers are position-sensitive proportional counters primarily intended for the measurement of soft beta radioactivity from ^{3}H, ^{14}C, and ^{32}P. CX 162C, at 2

361. IN/US offers RITA for sale throughout the United States through sales representatives. CX 162C, at 2.

362. IN/US has made the following sales in the United States of a Radioactivity Intelligent Thin-Layer Analyzer (RITA) imaging chromatogram analyzer exported to the United States by ISOMESS:

C
C
C
C

C
C
C
C

C
C
C
C

C
C
C

C
C
C
C

CX-162C, at 1-2.

C 363. In FY 1986, IN/US sold RITA imaging chromatogram analyzers. CX 126C.

364. IN/US demonstrated from February 1986 to July 1986 RITA to the following potential customers:

Date	Company

C

C

C

C

C

C

C

C

C

C

C

C

C

C

C

C

CX-162C, at 2-3.

C 365. At the following locations where

C :

C

C

C

C

C

C

C

C

C

CX 160C, at 2-3; Shulman, Tr. at 715-716.

366. **As evidenced by correspondence between IN/US and ISOMESS and**
C **the sales representatives of IN/US,**

C

C . CX 51, CX 90, CX 93, CX 95, CX 96, CX 97.

367. **As evidenced by correspondence between IN/US and ISOMESS and**
C **the sales representatives of IN/US,**

C

C . CX 91, CX 94.

B. <u>Radiomatic</u>

368. Radiomatic offers the Model RS TLC scanner imaging chromatogram analyzer for sale throughout the United States. CX 163C, at 4.

369. The Model RS TLC scanner imaging chromatogram analyzer and the Bioscan imaging chromatogram analyzer are primarily intended for the measurement of soft beta radioactivity from ^{3}H, ^{14}C, or ^{32}P. CX 163C, at 2.

370. Most of the potential customers in the United States for the imaging chromatogram analyzers sold by Bioscan and Radiomatic desire to measure soft beta radioactivity from ^{3}H, ^{14}C, or ^{32}P. CX 163C, at 2.

371. The Model RS TLC scanner imaging chromatogram analyzer and the Bioscan imaging chromatogram analyzers have directly competed and continue to directly compete for sales to some of the same potential customers in the United States. CX 163C, at 5.

372. Radiomatic has made the following sales in the United States of a Model RS TLC scanner imaging chromatogram analyzer:

DATE	PLACE	QUANTITY	PRICE

C
C
C
C
C
C
C
C
C
C
C
C
C
C
C
C
C
C
C
C

C Some of the imaging chromatogram analyzers referenced above

C . Prices

were supplied during the hearing by Mr. Reich. CX 163C, at 3-4.

C 373. At the following locations where T

C :

C

C

C

C

C

C

C

C

C

C

C

C

C

C

C

C

C

C

CX 160C, at 1-2; Shulman, Tr. at 710-714.

374. As evidenced by its responses to various discovery inquiries

C during this investigation,

C . CX 108C, Responses to Interrog. Nos. 8, 11 and 17; CX 109C, Responses to Interrog. No. 3; CX 127C.

C 375. In FY 1985, Radiomatic sold Model RS TLC scanner imaging chromatogram analyzers. CX 109C.

C 376. In FY 1986, Radiomatic sold Model RS TLC scanner imaging chromatogram analyzers. CX 109C, CX 127C.

377. As evidenced by <u>inter alia</u> the Radiomatic/Radioanalytic 1986

C business plan,

C

C . CX 89, CX 98.

378. Radiomatic has demonstrated between January 1986 to June 30, 1986 the Model RS TLC scanner imaging chromatogram analyzer to the following potential customers:

DATE	COMPANY
C	
C	
C	
C	
C	
C	

C

C

C

C

C

C

C

C

C

C

CX 163C, at 4-5.

VIII. CONCLUSIONS OF LAW

1. The U.S. International Trade Commission has jurisdiction over the subject matter of this investigation. FF 1.

2. The '057 patent is not anticipated by prior art. Opn. at 9-11.

3. Claim 9 of the '057 patent is invalid for lack of enablement. Opn. at 33-36

4. An interpreted herein, claim 5 of the '057 patent is nonobvious. Opn. 12-33.

5. Patent infringement is an unfair act or method of competition under 19 U.S.C. § 1337. In re Von Clemm, 108 U.S.P.Q. 371 (C.C.P.A. 1955).

6. Respondents Radiomatic and IN/US have either imported and/or sold chromatogram analyzers in the United States. Opn. at 50.

7. The chromatogram analyzers of respondents Isomess, Aloka, Radiomatic and IN/US do not infringe claims 5, 8 and 9 of the '057 patent. Opn. at 37-49.

8. There is no domestic industry in this investigation because complainant does not exploit the '057 patent. Opn. at 51-52.

9. If there is a domestic industry, it is efficiently and economically operated. Opn. at 53.

10. If, contrary to the conclusion reached herein, the chromatogram analyzers of respondents Isomess, Aloka, Radiomatic and IN/US are finally determined to infringe claim 5 of the '057 patent, the importation and sale of these chromatogram analyzers has the effect or tendency to substantially injure the domestic industry as defined in this investigation. Opn. at 54-59.

11. There is no violation of section 337 of the Tariff Act of 1930, as amended, in the importation of certain chromatogram analyzers, or in their sale, by reason of infringement of claims 5, 8 and 9 of U.S. Letters Patent

No. 4,019,057 (Bram), the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States. Conclusions of Law 2-10.

IX. INITIAL DETERMINATION AND ORDER

Based on the foregoing opinion, findings of fact, conclusions of law, the evidence, and the record as a whole, and having considered all pleadings and arguments as well as proposed findings of fact and conclusions of law, it is the administrative law judge's INITIAL DETERMINATION (ID) that no violation of § 337 exists in the importation of certain chromatogram analyzers, or in their sale, by reason of infringement of claims 5, 8 and 9 of U.S. Letters Patent No. 4,019,057 (the '057 patent), the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States.

The administrative law judge hereby CERTIFIES to the Commission this Initial Determination, together with the record of the hearing in this investigation consisting of the following:

1. The transcript of the hearing, with appropriate corrections as may hereafter be ordered by the administrative law judge; and further

2. The exhibits accepted into evidence in this investigation as listed in the attached exhibit lists.

In accordance with Rule 210.44(b), all material found to be confidential by the administrative law judge under Rule 210.6 is to be given in camera treatment.

The Secretary is instructed to serve a public version of this Initial Determination upon all parties of record and the confidential version upon counsel who are signatories to the protective order issued by the administrative law judge in this investigation, and the Commission investigative attorney. To expedite service of the public version, counsel are hereby ordered to serve on the administrative law judge by no later than April 14, 1987, a copy of this ID with those sections considered by the party to be confidential bracketed in red.

This ID shall become the determination of the Commission 45 days after its date of service unless the Commission within those 45 days shall have ordered review of this ID, or certain issues herein, pursuant to Rule 210.54(b) or 210.55. 19 C.F.R. § 210.53(h).

Sidney Harris
Administrative Law Judge

Issued: April 9, 1987

CERTAIN ELECTRONIC CHROMATOGRAM
ANALYZERS AND COMPONENTS THEREOF

INV. NO. 337-TA-251

CERTIFICATE OF SERVICE

I, Kenneth R. Mason, hereby certify that the attached Initial Determination (Public Inspection) was served upon Jeffrey L. Gertler, Esq., and Cheri Taylor, Esq., and upon the following parties via first class mail, and air mail where necessary, on April 21, 1987.

Kenneth R. Mason, Secretary
U.S. International Trade Commission
701 E Street, N. W.
Washington, D.C. 20436

FOR COMPLAINANT BIOSCAN, INC.:

Frederick G. Michaud, Jr., Esq.;
Eric H. Weisblatt, Esq.
BURNS, DOANE, SWECKER & MATHIS
George Mason Building
Washington & Prince Streets
Alexandria, Virginia 22313-1404

RESPONDENTS

FOR ALOKA, CO.; RADIOMATIC INSTRUMENTS & CHEMICAL CO., INC.:

Mr. Andrew R. Reich
President
Radiomatic Instruments and Chemical Co., Inc.
5102 S. Westshore Boulevard
Tampa, Florida 33611

FOR ISOTOPENMESSEGERATE GmbH:

Dr. Edward Rapkin
President
IN/US SERVICE CORPORATION
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

GOVERNMENT AGENCIES:

Mr. Charles S. Stark
Antitrust Div./U.S. Dept. of Justice
Room 7115, Main Justice
Pennsylvania Avenue & Tenth Street, N.W.
Washington, D.C. 20530

Edward F. Glynn, Jr., Esq.
Asst. Dir. for Int'l Antitrust
Federal Trade Commission
Room 502-4, Logan Building
Washington, D.C. 20580

Darrel J. Grinstead, Esq.
Dept. of Health & Human Services
Room 5362, North Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Michael T. Schmitz
Chief Counsel
U.S. Customs Service
1301 Constitution Avenue, N.W.
Washington, D.C. 20229