

Appellant's Brief

BRIEF FOR APPELLANTS

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IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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CLERK

APPEAL NO. 88-1265

KINGSDOWN MEDICAL CONSULTANTS, LTD.
and E.R. SQUIBB & SONS, INC.,

Plaintiffs-Appellants,

v.

HOLLISTER INCORPORATED,

Defendant-Appellee

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS,
EASTERN DIVISION, HONORABLE JAMES F. HOLDERMAN

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ATTORNEYS FOR APPELLANTS

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CERTIFICATE OF INTEREST

The undersigned counsel of record for Kingsdown Medical Consultants, Ltd. and E. R. Squibb & Sons, Inc., (Plaintiffs-Appellants) furnishes the following list in compliance with Rule 8:

- (a) Kingsdown Medical Consultants, Ltd., a corporation of Great Britain.
E. R. Squibb & Sons, Inc., a corporation of Delaware.
- (b) Not applicable.
- (c) Kingsdown Medical Consultants, Ltd. and E. R. Squibb & Sons, Inc. are wholly-owned subsidiaries of Squibb Corporation, a corporation of Delaware having its headquarters in Princeton, New Jersey.
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Garland P. Andrews

RELATED CASES

There are no related cases currently before this Court or any other appellate court nor have there been any related cases previously before this Court or any other appellate court.

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THE FOLLOWING ABBREVIATION WILL BE EMPLOYED THROUGHOUT THE BRIEF:

"Ap."

Joint Appendix

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Plaintiffs-Appellants,

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HOLLISTER INCORPORATED,

Defendant-Appellee

BRIEF FOR PLAINTIFFS-APPELLANTS

STATEMENT OF ISSUES PRESENTED FOR REVIEW

1. Whether the district court erred as a matter of law in concluding that the patentee engaged in inequitable conduct by basing its conclusion on erroneous findings of materiality and intent.
2. Whether the district court erred as a matter of law when it found that but for the representation in the preliminary amendment claims would not have issued because the court's conclusion was based on clearly erroneous findings that the examiner did not examine the claims, clearly erroneous interpretations of expert testimony, and an erroneous interpretation of claim language.
3. Whether the district court's finding that the examiner did not examine Claim 9 of the patent-in-suit for compliance with 35 U.S.C. § 112 was clearly erroneous because the evidence establishes that the examiner performed his statutory duty and examined all of the claims at least twice subsequent to the preliminary amendment which added Claim 9.
4. Whether the district court erred as a matter of law in finding that applicant's attorney committed inequitable conduct by representing that a claim presented in a preliminary amendment in a Rule 60 continuation application was allowable and allowed, when the applicant's attorney had unknowingly and mistakenly included in the preliminary amendment the text of the claim which contained allowable subject matter but had been rejected under 35 U.S.C. § 112 for indefiniteness rather than the text as subsequently amended and allowed in the original application, and

further, in finding that the attorney's failure to catch the mistake constituted gross negligence.

5. Whether the district court erred as a matter of law when it held that a ministerial error relating to the definiteness of claim language was gross negligence sufficient to support a finding of inequitable conduct.
6. Whether the district court's finding that the examiner must rely upon the representations of the applicant in a continuation application concerning the status of claims in the parent application was an error of law.
7. Whether the district court's finding that the conduct of applicant's attorney was sufficient to constitute an intent to mislead is clearly erroneous when considered in light of the nature of the error and because the court improperly relied on events occurring after issuance of the patent.

STATEMENT OF THE CASE

I. NATURE OF THE CASE, COURSE OF PROCEEDINGS AND DISPOSITION IN THE COURT BELOW

This action by Kingsdown Medical Consultants Ltd. and E. R. Squibb & Sons, Inc., owner and exclusive licensee, respectively, (Ap. 2399-400, 2465-66) [hereinafter "Squibb"] is for infringement of Claims 2, 4, 5, 9, 10, 12, 13, 14, 16, 17, 18, 27, 28, and 29 of U. S. Patent No. 4,460,363 ("the '363 patent") by the "Hollister Two-Piece Ostomy System" manufactured and sold by Hollister Incorporated [hereinafter "Hollister"]. The action proceeded to trial during the periods of September 21-October 2,

1987 and January 5-19, 1988. On February 12, 1988, judgment¹ was entered holding the '363 patent unenforceable. (Ap. 3-5) The judgment was based on a conclusion that Squibb's attorney had committed inequitable conduct by representing in a preliminary amendment in a Rule 60 continuation application that two of the claims, which are now Claims 9 and 24 of the patent-in-suit, had been allowable and allowed in the parent application, when in fact the particular claims presented, although held by the Examiner to contain allowable subject matter, had been rejected as indefinite under 35 U.S.C. § 112 and subsequently amended and allowed. The district court found that Squibb's attorney either intended to deceive the Patent and Trademark Office [hereinafter "PTO"] or his failure to catch the error during the prosecution of the continuation application was gross negligence. (Ap. 6-19) The judgment specifically did not address infringement or validity issues. (Ap. 3-5) Squibb has appealed from the judgment of unenforceability.

II. STATEMENT OF FACTS

A. Ostomy Appliances

Various medical conditions caused by trauma and disease require intestinal surgery techniques which create an opening in the abdominal wall of a patient for waste release. Patients who undergo this surgery are called "ostomates" or "ostomy patients", and are treated by physicians and enterostomal therapists. (Ap. 4149-52, 4183-87) The surgically created opening is called a

¹This judgment amended the prior judgment entered January 25, 1988. (Ap. 1-2)

stoma. Depending upon the type of surgery, the stoma will release either liquid or semi-solid body waste from the patient, usually at an uncontrolled rate. (Ap. 1298-1301, 4153-58)

Numerous medical appliances have been developed through the years to collect these body wastes from the patient. The medical appliances developed varied from bulky rubber multi-piece products held in place with a belt to one-piece plastic bags adhesively applied to the skin surrounding the stoma. (Ap. 4159, 4197-220)

B. The Squibb Invention

Ostomy appliances slowly improved, but the need remained for an appliance that would remain secured to the body around the stoma in a liquid, gas, and odor-proof seal, that could be easily removed, applied and emptied, and would provide easy access to the stoma for medical inspection and hygienic purposes. Skin irritation and the bulk of the appliance under clothing were also of primary concern. (Ap. 4160-61, 4330-31)

The patent-in-suit is directed to a two-piece ostomy appliance which comprises a pad and a detachable pouch. The pad is secured to the body of an ostomate about the stoma. A stoma opening extends through the pad, and a coupling ring encircles the stoma opening on the pad. (Ap. 583-97) Waste collection pouches of various sizes and shapes having matching coupling rings encircling the openings of the pouches are then attached to the coupling ring on the pad. (Ap. 1403-58, 4699-701) The annular coupling rings which encircle the openings in the pad and bag easily snap together and provide a liquid, gas, and odor-

proof seal between the bag and pad. The coupling remains secure during normal activities. The pad can remain in place on the body for several days and by disengaging the coupling, bags can be removed and the stoma observed. (Ap. 4161-63, 4230-33, 4728) One of the coupling rings is two opposed walls of closed loop annular channel form having a retaining bead on the inside outer leg of the channel. The other coupling ring is a rib or projection dimensioned to be gripped between the opposed channel walls of the annular coupling and has a thin resilient seal strip extending inwardly therefrom and a bead on its outer surface which interacts with the channel walls to provide engagement. (Ap. 583-97)

The two-piece device of the '363 patent was invented in England by Peter Steer (Ap. 1334-35, 2516-18, 4329-37, 4373-74) and John Edwards, inventors working for Kingsdown Medical Consultants. (Ap. 4350-51) The parent application of the '363 patent was filed February 27, 1978 based upon four British applications. (Ap. 726-1066) A continuation application was filed on July 2, 1982 which led to the '363 patent. (Ap. 598-725) Squibb introduced the two-piece appliance in the U.K. in March 1978 and in the United States in November 1978 under the trademark "Sur-Fit®". (Ap. 1290-91, 2508-15, 4380-81, 4663-67) Prior to this time, Squibb was not a factor in the ostomy market. (Ap. 5548, 5563)

C. The Prosecution History of the '363 Patent Pertinent to The Alleged Inequitable Conduct

The trial court ruled that but for Squibb's inequitable conduct independent Claim 9² of the '363 patent would not have issued, but rather claims having language such as that in Claim 27 would have issued. The trial court ruled that this language in Claim 9 issued solely because of a misrepresentation made by Squibb's attorney in the preliminary amendment of a Rule 60 continuation application: (Ap. 13)

9. An ostomy appliance comprising a pad or dressing having a generally circular aperture for passage of the stoma, said pad or dressing aperture encircled by a coupling member and an ostomy bag also having a generally circular aperture for passage of the stoma, said bag aperture encircled by a second coupling member.... (Ap. 596)

The evidence showed that the attorney hired by Squibb to prepare the preliminary amendment mistakenly indicated that the claim which led to Claim 9 had been indicated to be "allowable" and "allowed", when in fact the specific claim had been indicated to contain allowable subject matter but had been rejected under 35 U.S.C. § 112 for indefiniteness over the meaning of the word "encircled". (Ap. 644-45, 4518) The district court held that the failure of the Squibb attorney to catch this mistake constituted inequitable conduct. (Ap. 13, 17)

The first office action of parent application Serial No. 881,274 (filed February 27, 1978), dated March 26, 1979, contained restriction requirements and art rejections. (Ap. 726,

²Note the court's opinion was directed to Claim 9, and although the court's comments would also apply to Claim 24, we focus on Claim 9 as the court did.

890-95) None of the claims were rejected on the grounds of indefiniteness, although original Claim 1 contained the following language:

1. A coupling for an ostomy appliance comprising a pad or dressing having an aperture for passage of the stoma encircled by a coupling member and an ostomy bag also having an aperture for passage of the stoma encircled by a second coupling member.... (Ap. 744)

Examiner Wallen issued an office action on November 5, 1979 (Ap. 948-50) rejecting all claims over the art except 6-11 and 13-15. There was no rejection of Claim 1, upon which Claim 6 depended, under 35 U.S.C. § 112. The office action stated:

III. Claims 6-11 and 13-15 would be allowed in independent form; these claims are rejected under 35 U.S.C. § 112, second paragraph, as they depend from rejected claims. (Ap. 949)³

The next amendment, which was signed January 17, 1980 (Ap. 952-60), cancelled Claims 1, 2 and 4, added Claim 41 and amended Claims 3 and 5 so that Claim 6 ultimately depended from Claim 41:

41. A coupling for an ostomy appliance comprising a pad or dressing having an aperture for passage of the stoma encircled by a coupling member and an ostomy bag also having an aperture for passage of the stoma encircled by a second coupling member.... (Ap. 953)

The next office action mailed May 5, 1980 (Ap. 964-67) included the following:

Claims 41 and 42 are rejected under paragraph 2 of 35-U.S.C.-112. In these claims, it appears that the coupling member encircles the pad or dressing. Claims 3, 5-18 and 43-45, being dependent on claims 41

³Defendant's expert, Jere Sears, confirmed that the examiner read Claim 6 before deeming it allowable in independent form. (Ap. at 5267)

and 42 are also rejected under paragraph 2 of 35-U.S.C.-112.

Claims 6-11 and 16-18 would be allowed in independent form, as previously indicated. They stand rejected under paragraph 2 of 35-U.S.C.-112, as dependent from rejected claims. (Ap. 965)

The next treatment of Claim 6 was in an Examiner Interview Summary Record mailed July 28, 1980 (Ap. 985) wherein it was stated:

Agreed that in paper No. 11, page 2, paragraph 2 of the final rejection, the claims previously allowed should be 6-11 and 13-15 instead of 16-18. (Ap. 985)

In the first amendment after final (Ap. 986-97) applicant stated:

Allowed dependent Claim 6 has been rewritten in independent form as Claim 50...and rejected Claims 12 (52) and 16 to 18 now depend from allowable Claim 50. Accordingly, it is submitted that all of Claims 6 to 11, 13 to 18 and 50 to 52 are in condition for allowance. (Ap. 989)

Claim 50 (hereinafter "unamended 50") read as follows:⁴

50. A coupling for an ostomy appliance comprising a pad or dressing having a generally circular aperture for passage of the stoma, said pad or dressing aperture encircled by a coupling member and an ostomy bag also having a generally circular aperture for passage of the stoma, said bag aperture encircled by a second coupling member, one of said coupling members being two opposed walls of closed looped annular channel form and the other coupling member of closed loop form having a rib or projection dimensioned to be gripped between the mutually [sic] opposed channel walls when said coupling members are connected, said rib or projection having a

⁴This is the claim which was placed in the preliminary amendment of the continuation application as Claim 43 which became Claim 9 of the '363 patent.

thin resilient deflectible seal strip extending therefrom, which, when said rib or projection is disposed between said walls, springs away therefrom to sealingly engage one of said walls, and in which each coupling member is formed of resilient synthetic plastics material. (Ap. 987)

Thus, unamended Claim 50 clarified that the coupling member encircles only the aperture on the pad to overcome the previous rejection of Claim 41. This language had been held acceptable twice previously in the first and second office actions. (Ap. 890-95, 948-50, 4657-59, 5787)

The next office action of September 5, 1980 (Ap. 999-1002) treated unamended Claim 50 as follows:

Claims 42, 50, 51, 53 and 54, and dependent claims 43-45, 7, 8, 52, 13-18, 10, 11, and 40, are rejected under paragraph 2 of 35 U.S.C. 112. "said pad or dressing aperture encircled by a coupling member" (claims 42, 50, 51) and "encircling said aperture" (claims 53 and 54) appear inaccurate from the drawings. A circle is a planar figure, and anything "encircled" must therefore be coplanar with the circle. Clearly from the figures the coupling member is cylindrical, not planar, and cannot "encircle" the pad aperture it is not coplanar with. "said bag aperture encircled by a second coupling member" (claims 42, 50, 51), by similar reasoning, is also considered inaccurate. Because the second coupling member is not coplanar with the bag aperture, it cannot "encircle" the aperture. The above listed dependent claims, by nature of their dependency, are inherently indefinite and therefore rejected....

....

Claims 50, 51, dependent Claims 7, 8, 13-18, 52, 10, and 11 are drawn to allowable subject matter, as previously indicated. Note, however, they stand rejected under paragraph 2 of 35 U.S.C. 112. (Ap. 1001-02)

In the next amendment which was signed November 26, 1980

(Ap. 1004-12), Claim 50 was amended as follows:

50. (amended) A coupling for an ostomy appliance comprising a pad or dressing having a body contacting surface and an outer surface with a generally circular aperture for passage of the stoma extending through [.] said pad or dressing, [aperture encircled by] a coupling member extending outwardly from said outer pad or dressing surface and encircling the intersection of said aperture and said outer pad or dressing surface, and an ostomy bag also having a generally circular aperture in one bag wall for passage of the stoma [, said bag aperture encircled by] with a second coupling member affixed to said bag wall around the periphery of said bag wall aperture and extending outwardly from said bag wall, one of said coupling members being two opposed walls of closed looped annular channel form and the other coupling member of closed loop form having a rib or projection dimensioned to be gripped between the mutually opposed channel walls when said coupling members are connected, said rib or projection having a thin resilient deflectible seal strip extending therefrom, which, when said rib or projection is disposed between said walls, springs away therefrom to sealingly engage one of said walls, and in which each coupling member is formed of resilient synthetic plastic material. (Ap. 1005)

In an advisory action on Form PTOL-303 Paper No. 17 mailed December 22, 1980 (Ap. 1013), the Examiner checked box 2:

Newly proposed or amended claims 50, 7, 8, 13-18, 52, 51, 10, 11 would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

He also checked box 3 to the following effect:

Upon the filing of an appeal, the proposed amendment will be entered and the status of the claims in this application would be as follows: Claims 50, 7, 8, 13-18, 52, 51, 10, 11 would be allowable.

No further action as to Claim 50, 7, 8, 52, 13-18, 51, 10 and 11 was taken in the parent case other than to mention they were allowed. (Ap. 1015, 1024, 1040-42). Broader claims including claims to the ostomy bag alone were appealed. (Ap. 1014, 1015, 1024)

Squibb's attorney, Mr. Davis, consulted with outside attorney Melvin Goldenberg to prepare a continuation application, instead of awaiting the appeal decision, because Hollister had entered the market with its two-piece ostomy system. In the accompanying preliminary amendment, all of the originally filed claims were cancelled, and newly-drafted broader claims and claims from the parent application were added, apparently according to Squibb's instructions to file the broader claims with the allowed claims from the parent case. (Ap. 638-45, 2089-90, 2122, 4512-15, 4518)

The preliminary amendment, under "Remarks" (Ap. 644-45), stated:

Claims 43 through 63 are claims in the original application which were indicated as allowable, in some cases being rewritten where the allowed claim depended from a rejected claim. A table showing the number of the claim as it appears in this amendment and the number of the claim as allowed in the original application follows:

<u>Number of Claim as Allowed In Original Application</u>	<u>Number of Claim In This Amendment</u>
50	43
51	58
55 and 43	61

Mr. Davis signed the preliminary amendment prepared by Mr. Goldenberg but did not notice that it included unamended Claims 50 and 51 of the parent application rather than amended Claims 50 and 51. (Ap. 4514, 4563-64) Mr. Davis reasoned that he probably did not notice the mistake because he felt the amended and unamended claims were of substantially the same scope. He testified that he had not originally agreed with the Examiner's definition of encircled but amended the claims in the parent because the amendment did not affect the coverage of the claims. (Ap. 4577, 4611-12, 4586-87, 4609-10)

Squibb filed a detailed prior art statement on January 28, 1983 in the continuation case. (Ap. 646-61) The three pages of Form PTO-1449 accompanying the amendment were initialed, signed and dated June 21, 1983 by Examiner Wallen. (Ap. 659-61) Along with the prior art statement, Squibb filed a petition to make special. (Ap. 663-82) The petition stated that Hollister's two-piece ostomy system was being marketed and would infringe the claims presented. (Ap. 663-64)

On June 23, 1983 a notice of allowance was mailed (Ap. 687) before the approval of the petition to make special was mailed on June 30, 1983. (Ap. 684) There are two notice of allowability forms PTOL-37 in the file which are apparently identical except that one bears two dates: June 23, 1983 and July 18, 1983. The form indicates the claims were allowed in view of the applicant's communication filed July 2, 1983. Box 5 was also checked, "Note attached list of art cited by applicant, PTO-1449." (Ap. 691-92)

On August 27, 1983, a Rule 312 amendment was filed (Ap. 696) with two PTO-1449 forms citing additional references to those

cited on June 21, 1983 along with the application. (Ap. 659-61) The application file was thereafter misplaced in the PTO, and on January 14, 1984 applicant finally received a communication that the amendment was entered. (Ap. 704) The form PTO-1449 was initialed, dated, and signed January 11, 1984 by Examiner Wallen (Ap. 705-06), and a duplicate form was again initialed, dated, and signed by Examiner Wallen on March 22, 1984. (Ap. 714-15) The Examiner's search notes indicate searches were done on June 21, 1983 and October 3, 1979. (Ap. 723) The Examiner made the notation "(see parent)" with reference to the October 3, 1979 search. Id.

D. History of the Controversy

Prior to the introduction of Squibb's first commercial ostomy system, the Sur-Fit® two-piece ostomy system, Hollister had been the leader in the ostomy appliance marketplace (Ap. 4235), but had no multi-piece appliance for use outside the hospital. (Ap. 2346-47, 4263-66) Squibb's Sur-Fit® sales went from 20,000 body side units in November 1978 to nearly one million units in December 1986 and was a commercial success. (Ap. 1395-1400, 4713-16, 4730) Hollister, aware of the success of the Sur-Fit® system, began a research and development program to develop a two-piece ostomy system. (Ap. 1089-1196, 1865, 2054-58, 4963-65, 5072-73) After multiple design attempts and failures, Hollister introduced to the market in March or April of 1982, a two-piece system developed from the Squibb product. (Ap. 663, 4718, 2082-84, 5006-10, 5018-19, 5091-105) The Hollister appliance uses the same type coupling rings as the Squibb

appliance, but differs from the Squibb appliance in that the coupling rib on the pad is connected to the pad via the "floating flange", an annular web connecting the base of the connecting rib and the body side pad. (Ap. 1302-03, 1306-07, 1459-75, 2467-71, 2476-77, 4509-10, 4236-37, 4966, 5680) The outer periphery of the annular rib is attached to the base of the rib and the inner periphery of the flange is attached around the aperture in the pad on the outer surface of the pad. Thus, in a normal lay-flat position, the ring rests upon the pad but the flange allows thumbs to be squeezed under the ring during connecting procedures. (Ap. 1330-33) Both the Squibb and the Hollister body side pads carry the rib-shaped coupling ring and the bags carry the annular channel coupling. (Ap. 4476-510) The Hollister bag or faceplate coupling engages with the Squibb faceplate or bag coupling, a fact at one time promoted by Hollister's own literature. (Ap. 1310-15, 1326-29, 1459, 1795-97, 1817-19, 1831-32, 2077-80, 2301-02, 2307-08, 2478-84, 2352-53, 4238-41, 4719-20)

When it introduced its two-piece ostomy products, Hollister was aware not only of Squibb's Sur-Fit[®] product but also of Squibb's foreign patents and Squibb's parent application Serial No. 881,274.⁵ (Ap. 1863-64, 2838-46, 3106-08, 3120-21, 3133-35, 3209-15) Squibb warned Hollister that it had a patent pending as well as corresponding issued patents in the United Kingdom. (Ap. 1067-87) Squibb filed suit for patent infringement on July 17,

⁵The application serial number was referenced in another patent issued to Squibb in 1980, U.S. No. 4,232,642. (Ap. 1256-61) Hollister was aware of '642 as of November 11, 1980 (Ap. 1864), thus allowing Hollister to periodically request the status of 881,274 and to obtain the prosecution history once it was abandoned. (Ap. 3226-27)

1984, the day the '363 patent issued. (Ap. 584) By that time, Hollister's attorneys had already performed exhaustive patent searches in the medical art (Ap. 2951-52, 2953-3051, 5485-93), but had failed to locate any patents covering the interlocking flange arrangement of the Sur-Fit® products. (Ap. 3052-53) Searches had also been done in an attempt to support an unpatentability position in the container art. (Ap. 3106-08, 3228-30, 5493-95) Hollister's attorneys obtained copies of the abandoned parent file and concluded that amended Claims 50 and 51 would cover the Hollister product with the floating flange. (Ap. 3955-65, 5523) The attorneys reasoned that the floating flange distinction was not strong. (Ap. 3955, 5524)

Normal discovery occurred through 1986 and discovery closed. The pretrial order was filed December 29, 1986 (Ap. 76) and a pretrial conference was held on January 15, 1987. By this time, Hollister had neither alleged this form of inequitable conduct nor that Claim 9 was invalid under 35 U.S.C. § 112 for indefiniteness. (Ap. 88-91, 1943-48, 1959-65, 1966-93, 2064-76) In March 1987, Hollister supplemented its interrogatory answers and moved to amend its counterclaim to allege inequitable conduct. (Ap. 1994-2049) In April the counterclaim was amended. (Ap. 256-67) Hollister alleged it only "discovered" the inequitable conduct at that time.

Until Hollister amended its counterclaim to specify its theory that the mistake in the preliminary amendment constituted inequitable conduct, as its answers to the discovery requests cited supra indicate, it did not assert that Claim 9 was invalid under § 112 on the theory that the encircled language was

indefinite. Even when answering requests for admissions, Hollister admitted that its coupling encircled apertures in both the pad and bag of its commercial product. (Ap. 1876) The trial court, over Plaintiffs' objection, allowed the admissions to be changed at trial. (Ap. 1881-83, 4843-44, 4883-84)

SUMMARY OF THE ARGUMENT

Squibb's attorney in charge of prosecuting the patent-in-suit conformed to the duty of candor and good faith and the duty to disclose information he was aware of to the PTO.

The trial court's conclusion that Squibb's attorney intended to deceive the Examiner by misrepresenting the status of Claim 9 because he must have perceived Hollister's noninfringement defense is totally without factual basis. The uncontroverted evidence is that Squibb's attorney was not aware of the error. Furthermore, Claim 9 was presented together with several other broader claims including Claims 2, 4, and 5, and narrower Claims 27 and 28 which are all clearly infringed by the Hollister device. The intent finding fails because the trial court misinterpreted testimony relating to the infringement of Claims 9 and 27 and refused to conduct an infringement analysis of all the claims in the suit.

The trial court's determination that but for the misrepresentation made by Squibb's attorney in the preliminary amendment of a Rule 60 continuation application, Claim 9 would have never issued is an error as a matter of law since the court refused to make a proper validity determination of Claim 9. Hollister did not challenge the definiteness of Claim 9 during the discovery

period in this lawsuit and only challenged its definiteness after it found the error in the preliminary amendment. Claim 9 when read in light of the patent, satisfies all of the requirements of 35 U.S.C. § 112. In addition, the evidence shows that the Examiner did in fact examine Claim 9 before allowing it in the continuation case.

The failure of Squibb's attorney to catch the error of an outside attorney who compiled the table of previously allowed claims in the preliminary amendment was at most an act of simple negligence. No reasonable attorney would have caught this error during the subsequent prosecution of the case because it is not apparent from reading Claim 9. Furthermore, there was no reason to proofread the claims against the parent during the subsequent prosecution. The opinion of both Hollister's and Squibb's experts is that there was no deceptive intent involved in presenting the preliminary amendment. A conclusion of deceptive intent or gross negligence based upon a single act of simple negligence is error as a matter of law. Even if Claim 9 is invalid under 35 U.S.C. § 112, that coupled with an act of simple negligence is insufficient to support a finding of inequitable conduct.

ARGUMENT

- I. THE DISTRICT COURT ERRED AS A MATTER OF LAW IN CONCLUDING THAT THE PATENTEE ENGAGED IN INEQUITABLE CONDUCT BECAUSE IT BASED ITS CONCLUSION ON ERRONEOUS FINDINGS OF MATERIALITY AND INTENT

The case at bar presents a fact situation of first impression. If the district court's decision is allowed to stand, then a great injustice will be done to the class of patentees as a

whole, because infringers will be enabled by this decision to render patents unenforceable by finding imperfections based upon ministerial errors in the prosecution that have not taken anything from the public domain.

Inequitable conduct is a legal conclusion based on balancing the factual findings of materiality and intent. American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1364, 220 U.S.P.Q. 763 (Fed. Cir.), cert. denied, 469 U.S. 821 (1984). The standard of review on a legal conclusion is correctness or error as a matter of law. In re Caveney, 761 F.2d 671, 674, 226 U.S.P.Q. 1 (Fed. Cir. 1985).

The underlying factual findings of materiality and intent must be proven by clear, convincing and unequivocal evidence. In re Jerabek, 789 F.2d 886, 889, 229 U.S.P.Q. 530 (Fed. Cir. 1986). See also Orthopedic Equipment Co. v. All Orthopedic Appliances, Inc., 707 F.2d 1376, 1383, 217 U.S.P.Q. 1281 (Fed. Cir. 1983).

Recently this Court reiterated that the inequitable conduct defense was subject to strict standards of proof:

"Inequitable conduct" is not, or should not be, a magic incantation to be asserted against every patentee. Nor is that allegation established upon a mere showing that art or information having some degree of materiality was not disclosed. To be guilty of inequitable conduct, one must have intended to act inequitably.

FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415, 5 U.S.P.Q.2d 1112 (Fed. Cir. 1987).

Materiality and intent are questions of fact. Id.⁶ An appellate court reviews factual findings under the clearly erroneous standard. Id. A finding is "clearly erroneous" when the reviewing court, on the entire evidence, is left with the definite and firm conviction that a mistake has been committed. SSIH Equipment S.A. v. Int'l Trade Comm'n, 718 F.2d 365, 381, 218 U.S.P.Q. 678 (Fed. Cir. 1983).

A. The Finding Of Actual Intent Is Clearly Erroneous

A finding of intent must be based upon clear and convincing evidence of either actual intent to deceive the PTO or negligence based on such willful, wanton or reckless misconduct, or such utter lack of all care so as to rise to the level of "gross" negligence that is not countervailed by evidence of subjective good faith. FMC v. Manitowoc, 835 F.2d at 1415-16; Machinery Corp. of America v. Gullfiber AB, 774 F.2d 467, 473, 227 U.S.P.Q. 368 (Fed. Cir. 1985) (gross negligence under § 285 defined).

Although direct evidence of deliberate scheming to defraud the PTO is not requisite, see American Hoist, 725 F.2d at 1363, intent is a distinct element of inequitable conduct that cannot be presumed from materiality alone. Rather, the factfinder is required to "evaluate all the facts and circumstances in each case". KangaROOS U.S.A. v. Caldor, Inc., 778 F.2d 1571, 1577, 228 U.S.P.Q. 32 (Fed. Cir. 1985); N.V. Akzo v. E.I. Du Pont de Nemours & Co., 810 F.2d 1148, 1153, 1 U.S.P.Q.2d 1704 (Fed. Cir. 1987).

⁶ However, when the "but it may have" standard is used to assess materiality, the conclusion is a legal one. See infra pp. 29-30.

The alleged evidence of actual intent to deceive the PTO was stated by the district court to be that Mr. Davis viewed the Hollister commercial device and "must have perceived" in March or April of 1982 that Hollister would argue that the floating flange would not infringe the then existing claims of the parent application. (Ap. 9-10, 13-16) The court then speculated that the Squibb attorney intentionally filed unamended Claim 50 in the continuation application in order to obtain patent coverage over the Hollister device. See id.

It is clearly erroneous for the court to have inferred actual intent from these incredible assumptions and to infer that Mr. Davis instituted a deliberate scheme to defraud the PTO by filing a claim in the continuation case that he knew had been rejected under 35 U.S.C. § 112, while attempting to mislead the examiner into believing he was actually filing a different claim. Intent may not be found by drawing an inference on other inferences but requires clear and convincing evidence. FMC v. Manitowoc, 835 F.2d at 1417. The inference that there was a deliberate scheme to defraud is refuted by the complete story of Claim 9 illustrated in the prosecution histories. The evidence demonstrated that amended Claim 50, as well as unamended Claim 50, reads on the accused device. (Ap. 4483-86, 4549-52) Squibb, in fact, secured allowance of new Claims 1-8 which are much broader in scope than either unamended or amended Claim 50. (Ap. 596) Mr. Davis, therefore, had no motivation to try to trick the PTO into allowing unamended Claim 50.

The trial court was persuaded by the argument of Hollister's attorney, not the evidence. Hollister's own expert witness, Jere

Sears, a former PTO staff attorney and deputy solicitor, (Ap. 5178-84) testified:

Now, frankly, I don't have enough knowledge of what went on here to say that anybody harbored true deceptive intent. You can't get that from the Patent Office records, and it doesn't come through to me from whatever Steve Davis has testified to. (Ap. 5236)

Mr. Sears confirmed on cross-examination that he saw no evidence of actual deceptive intent on the part of Mr. Davis. (Ap. 5279-80)⁷ Squibb's expert, Mr. Arnold, saw no evidence of deceptive intent. (Ap. 5816-17, 3296, 3297) Mr. Davis testified that he did not intend to deceive the PTO. (Ap. 4563) Mr. Davis was not aware of the error until it was pointed out by Hollister in March 1987. (Ap. 4599, 4612, 4616, 5161) The evidence shows that Mr. Davis complied with the duty of candor, good faith and disclosure throughout the prosecution in submitting prior art to the PTO. (Ap. 5119-20, 3340, 5127-28, 5233)⁸

The court inferred intent and motive from an erroneous perception that Squibb needed the specific language of Claim 9 in order to achieve coverage of Hollister's device. The trial court specifically refused to make findings on infringement, yet it inferred intent from its analysis that Claim 9 (unamended Claim 50) would be infringed, but that Claim 27 would not be infringed.

⁷Mr. Sears did not become cognizant of the error by independently evaluating the prosecution history, but was told about it by Hollister's attorneys, after he had refused to testify in support of another fraud theory. (Ap. 5253-55, 5284)

⁸Further, when the Examiner made an error as to which claims he had found allowable, Mr. Davis brought it to his attention. (Ap. 4534-35, 985)

The trial court's limited, faulty and incomplete assessment of infringement renders its inference of intent improper.

First, if any other claim of the patent is infringed by the Hollister device, the inference of fraudulent motive must fail. The court did not consider whether any of the claims other than 9 and 27, including broader Claim 2, were infringed by the Hollister device. Thus, the inference of intent is erroneous.

Secondly, to the extent that the trial court performed an infringement analysis of Claim 9, it did so incorrectly. The first step in an infringement analysis is to construe the meaning of the claim. This is a question of law. While refusing to so hold, the district court inferred that Claim 9 would be invalid under § 112, as indefinite to one skilled in the art.⁹ But the court failed to recognize that claims are construed in light of the specification, drawings and the prosecution history, and are to be construed in such a manner as to preserve their validity if possible. See, e.g., ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929 (Fed. Cir. 1984).

It is clear that neither Hollister nor its attorneys ever had any trouble with the definiteness of Claim 9, until it needed to make that assertion to tie its inequitable conduct argument in a neat bundle. Squibb repeatedly posed interrogatories directed toward discovering Hollister's § 112 invalidity defenses throughout the lawsuit. Hollister understood the "encircling" language when these questions and requests for admissions were posed. See

⁹The trial court erroneously concluded that the rejection of unamended Claim 50 in the parent application under 35 U.S.C. § 112 was proper. (Ap. 16)

supra pp. 15-16. Only after Hollister found the inconsistencies in the continuation case's preliminary amendment, which Hollister's lead attorney stated in opening argument occurred only after his firm read the prosecution history 10 to 15 times (Ap. 4123), did it set forth the § 112 indefiniteness defense to conform with the late-presented theory of inequitable conduct. Id. However, one of the pieces of documentary evidence was never reconciled with this new theory. Hollister's outside attorney, Mr. Lungmus, had rendered an opinion that amended Claim 50 "covered" the Hollister device. (Ap. 5523-24, 3955-60)

The testimony of Mr. Arnold, a patent attorney with 40 years of experience, indicated that Claim 9 is in compliance with § 112. (Ap. 5664, 5671-72) Mr. Sears, Appellee's own expert witness, agreed that the definition of "encircled" in Webster's dictionary was not restricted to planar structures.¹⁰ (Ap. 5262-63) Stephen Davis, a Squibb attorney and former patent examiner, testified that he believes Claim 9 complies with the definiteness requirement of § 112. (Ap. 4471-75, 4609, 5158) The first examiner of the 881,274 application made no § 112 rejections of claims having language identical to Claim 9's "aperture encircled by" portion. Even Examiner Wallen, who made the § 112 rejection of unamended Claim 50, had previously found no § 112 defect in the identical language. The prosecution history of the continuation application indicates that Examiner Wallen examined

¹⁰"encircle...: 1: to form a circle about... enclose within a circle :SURROUND <a ring encircled her finger> <a camp encircled by enemies> 2: to make a circuit about: go around <as a hungry wolf might have encircled...the firelit camp of a hunter....>" (Ap. 2524 A-C)

Claim 43 at least two or three times and expressed no § 112 defect. See supra pp. 12-13.

Additionally, the district court committed legal error by using the Hollister commercial device in order to construe the meaning of the claim. See SRI International v. Matsushita Electric Corp., 775 F.2d 1107, 1118, 227 U.S.P.Q. 577 (Fed. Cir. 1985). The Hollister accused device employs a "floating flange" structure between the pad or dressing and the coupling of the body side faceplate. It is evident in the district court's opinion that the structure of the accused device was used to infer that Claim 9 of the patent-in-suit was invalid under § 112, because there is no recitation in the claim of an attachment means between the coupling member and the pad. This was not the reason that the Examiner rejected Claim 50 under § 112 in the parent case. (Ap. 5257, 1001-2) The trial court apparently derived this conclusion from a misunderstanding of the testimony of Squibb's expert witness, Tom Arnold. The court said:

I have examined again all of the evidence in the case, and in looking and comparing claim 9 with claim 27, which contains the appropriate amended language, using the point of intersection as the point at which the coupling member encircled the aperture of the pad or dressing, in examining those and comparing that to claim 9, by having the language in claim 9 that appears in claim 9, that allowed Mr. Arnold, the plaintiffs' expert, to testify that there is an omission in the claims about whether the coupling member, the body side coupling member, is secured to the pad or dressing.

The reason I say that is Mr. Arnold testified that, "By omitting that detail" -- and I'm now quoting from Mr. Arnold's testimony -- "By omitting that detail, the claim" -- referring to claim 9 -- "reads generically on whether it is connected

directly to the pad or dressing or is connected, in the alternative, through some intervening member, like the web system that gives them " -- referring to Hollister -- the floating flange that we have discussed."

Of course, I have to say I sat here in amazement when I heard that testimony, because there must be some intersecting point connecting the body side coupling member with the pad or dressing or the product would not work.

I believe that by reading out of the product some connecting point, a person skilled in the art, I believe, would have difficulty understanding, from reading the claims and comparing them to the specifications and the other figures in the patent, would have difficulty determining exactly what was covered by the patent. But I'm dealing with inequitable conduct, I'm not dealing with validity at this point. (Ap. 14-15)

The court's conclusion is a nonsequitur. Further, the court failed to appreciate Mr. Arnold's testimony as a whole. (Ap. 5661-780) Mr. Arnold testified that the scope of Claim 9 and Claim 27 were substantially the same, that the coupling member of the accused device included the floating flange or web, and that the Hollister construction would infringe either Claim 9 or Claim 27. (Ap. 5666-71, 5706-07, 5768-75, 1303):

In claim 9 there is no recitation, and in claim 27 -- I'm sure I'm remembering correctly, -- there is no recitation that the rib or projection -- that the rib or projection is secured to, directly to, the pad or dressing. There is an omission about whether it is secured to the pad or dressing.

By omitting that detail, the claim reads generically on whether it is connected directly to the pad or dressing, or is connected in the alternative through some intervening member, like the web system that gives them the floating flange we have discussed.

And so we find that the reality of claim 27, when read in light of the doctrine of equivalents, and the absence of any limitation in claim 9 that forces you to say the rib is connected directly to the pad or dressing -- remember, Mr. Sears acknowledged that that was so -- the two claims come out substantively the same -- if you apply the doctrine of equivalents, which says if they perform substantially the same function in substantially the same manner and by substantially the same means, that they are one and the same thing, no matter what the language is in the claim, if you apply that language to claim 27 and claim 9, the doctrine of equivalents says that the claims come out identically to each other rather than being substantially different.¹¹ (Ap. 5670-71)

Mr. Arnold was not stating that the coupling rib was not attached directly to the pad in Claim 9, in contrast to being attached directly to the pad in Claim 27, but that it made no difference how it was attached. (See Ap. 5670-71, 5784-85) Further, Mr. Arnold testified that Claim 27 was infringed either literally or under the doctrine of equivalents. (Ap. 5678-81, 1303-05) Literal infringement exists if one determines the floating flange is a portion of the "coupling rib". If one wishes to call it a separate element the device is still an equivalent. (Ap. 5679-80)

Fourth, the district court erroneously inferred that Claim 27 in the patent would not be infringed by the Hollister device, because the rib was not connected to the pad. The court failed to properly construe the claim or to address the question of

¹¹Mr. Arnold did correctly recall Mr. Sears' testimony concerning the interpretation of amended Claim 50 which contains the same language as patent Claim 27. Mr. Sears testified "I don't see any positive statement that the coupling is fixed to the pad." He also acknowledged that the PTO's § 112 rejection did not relate to the applicant's failure to cite where the coupling member is affixed to the pad. (Ap. 5256-60)

equivalents. Mr. Sears stated that the Hollister web attaches to the body pad at a point which encircles the intersection of the aperture and pad. (Ap. 5273-74) In short, the court relied on a partial consideration of infringement for its opinion but failed to make a complete and proper analysis of all aspects of infringement.

Even though a district court is not required to make findings on the issues of infringement and invalidity when inequitable conduct is found where there is no commonality of factual issues, Gardco Mfg., Inc. v. Herst Lighting Co., 820 F.2d 1209, 1213, 2 U.S.P.Q.2d 2015 (Fed. Cir. 1987), it is apparent that the district court in this instance based its intent finding on a cursory and inadequate evaluation of the claims. Thus, review of the judgment requires review of whether the trial court properly evaluated infringement and validity.

The court's suspicion that Mr. Davis must have perceived what Hollister's defense to infringement would be and that the language of Claim 9 was essential to prove infringement is totally unwarranted and not based upon the evidence, especially in view of the court's determination not to decide any issue of infringement or validity. Squibb simply did not need Claim 9 to prove the Hollister device infringed its patent and therefore the whole foundation upon which the trial court's conclusion of intent rests is unsound. The evidence is clear that the broader claims submitted with Mr. Davis' preliminary amendment are infringed by the Hollister device. Claims 2, 4, and 5 are

clearly infringed.¹² Claims 27 and 28 are also clearly infringed. (Ap. 4479-99, 4502-10) Squibb asserted Claim 9 at trial, not to obtain a windfall from a mistake, but because it was apparent that the error was unintentional and harmless and because it believed the claim was valid in spite of the error.

Further, the district court's § 112 analysis of Claim 9 does not even correspond to the rejection made in the parent case. The trial court inferred § 112 invalidity from the failure to recite a point of attachment between the pad and the coupling flange. In contrast, the § 112 rejection of unamended Claim 50 by the PTO was based on whether the term "encircling" could be applied to describe the relationship between noncoplanar structures, i.e., the cylindrical coupling and the flat pad. (Ap. 1001-02) Hollister's expert Mr. Sears agreed that the rejection pertained to the interpretation of the word "encircled." (Ap. 5256-61)

As will be apparent from the following section, while Squibb's attorney intended Claim 9 to include the immaterial limitations added in response to a previous rejection under 35 U.S.C. § 112, Claim 9 is not indefinite under the statute and is clearly allowable over the art. Therefore, while a mistake occurred, the public did not suffer. If the trial court felt Claim 9 was indefinite, it should have so ruled rather than hold the entire patent unenforceable without any evidence of intent. If Claim 9 were ruled to be indefinite under 35 U.S.C. § 112, because its inclusion in the patent was the result of simple

¹²Hollister did not present evidence to rebut infringement of these claims, other than to assert invalidity.

negligence, Squibb should be able to assert its remaining patent claims which are clearly infringed by the Hollister device.

Because the district court failed to use the correct standards, and because it employed speculation to infer intent, its finding of actual intent on the part of Mr. Davis was clearly erroneous.

B. The District Court Erred As A Matter Of Law When It Found That But For The Representation In The Preliminary Amendment Claims Would Not Have Issued Because The Court's Conclusion Is Based On Clearly Erroneous Findings That The Examiner Did Not Examine The Claims, Clearly Erroneous Interpretations Of The Expert Testimony And An Erroneous Interpretation Of Claim Language

There are four standards for determining materiality: (1) an objective "but for" standard; (2) a subjective "but for" standard; (3) a "but it may have" standard; and (4) PTO Rule 1.56(a). American Hoist, 725 F.2d at 1362.

The objective "but for" test relates to the actual materiality of the information at issue. In the case of withheld prior art, for example, if the claims are patentable over that art, the fraud allegation fails. In re Frost, 398 F. Supp. 1353, 1368, 185 U.S.P.Q. 729 (D. Del. 1975), modified on other grounds, 540 F.2d 601, 191 U.S.P.Q. 241 (3d Cir. 1976).

Under the subjective "but for" test, the question is whether the misrepresentations caused the particular examiner to issue the patent. American Hoist, 725 F.2d at 1362-63.

The next standard is "but it might have" which "endorses inquiry into whether the involved facts 'might reasonably have affected the examiner's decision as to patentability.'" Id. at 1362, quoting Genveto Jewelry Co. v. Lambert Bros., Inc., 542

F. Supp. 933, 939-40, 216 U.S.P.Q. 976 (S.D.N.Y. 1982). It is a legal conclusion as "[i]t is not a finding as to the existence of a certain thing, event, act, condition, etc." American Hoist, 725 F.2d at 1363 n.4.

The final standard is Rule 56 - "information 'is material where there is [1] a substantial likelihood that [2] a reasonable examiner [3] would consider it important [4] in deciding whether to allow the application to issue as a patent'." Id. at 1362 (emphasis in original).

The trial court held:

Plaintiff in this case has attempted to enforce the patent claim, the language of which was rejected, and but for being misled by the plaintiffs' conduct, part of the patent '53, the patent in suit, would not exist today. (Ap. 8).

The trial court's determination that "but for" the misrepresentation the claim would not have issued is based on its finding that the Examiner did not examine the claim, its misconstruction of Mr. Arnold's testimony from which it concluded that the claimed invention would be inoperative, and its misapplication of the basic rules of claim construction.¹³ (See Ap. 14-15) Where a mistake appears in a patent application which is not brought to the examiner's attention, the focus of the materiality inquiry is whether the nondisclosure of the true facts was important in allowing the patent to issue. See Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 750 F.2d 1569, 1570, 224 U.S.P.Q. 409 (Fed. Cir. 1984) (stating that even if examples given in a patent

¹³It is clear the court was applying the objective but for test rather than the subjective, because the examiner did not testify in this case. American Hoist, 725 F.2d at 1363 n.4.

were in fact prophetic but not delineated as such, a finding that such nondisclosure was material to the decision to allow the patent is still necessary).

This is a case of first impression -- an inequitable conduct finding based not upon the withholding of a reference or the misrepresentation of test data, but a mistaken inclusion of a claim in an amendment which all parties agree was indicated by the Examiner to contain allowable subject matter. Furthermore, as is clear from the evidence, the mistake can only be and was only detected from reading the prosecution history, not from reading the claim alone. The evidence shows that no one knew of the error or felt Claim 9 was indefinite under 35 U.S.C. § 112 until the error was discovered after the close of discovery. See supra pp. 22-24. Therefore, the mistake, while unfortunate and regrettable, does not cause any harm to the public. Claim 9 and its amended version, amended Claim 50, are of the same substantive scope. The trial court's reliance on Mr. Arnold's testimony relating to infringement is based on a misinterpretation of that testimony, takes that testimony out of context and is clearly erroneous. See supra p. 24-26. Furthermore, Hollister's expert, Mr. Sears, freely admitted that the issue of the attachment of the rib or projection to the pad was not the reason for the rejection of Claim 50 under 35 U.S.C. § 112. (Ap. 5256-57) There is no causal connection between the PTO's § 112 rejection and the trial court's reasoning that the claim does not meet § 112. Thus, because the court misinterpreted the testimony and the uncontested facts, the court's conclusion that "but for" the mistake in the preliminary amendment Claim 9 would not have

issued is an error as a matter of law. The court's "but for" conclusion is also clearly erroneous because the court ignored the papers initialed by the Examiner which constitute uncontroverted evidence that he examined all the claims of the continuation application.

- C. The District Court's Finding That The Examiner Did Not Examine Claim 9 Of The Patent-In-Suit For Compliance With 35 U.S.C. § 112 Is Clearly Erroneous Because The Evidence Establishes That The Examiner Performed His Statutory Duty And Examined All Of The Claims At Least Twice Subsequent To The Preliminary Amendment Which Added Claim 9

The trial court's finding of inequitable conduct was based in part upon its determination that the Examiner did not examine what became Claim 9 of the patent-in-suit. This finding is clearly erroneous and contrary to the evidence. In particular, the trial court found:

Now, during the course of this trial there was some testimony that perhaps at this point the examiner reexamined the language of claim 43 in the continuation application and found that now it was allowable. That, I believe, based upon the evidence of the examiner's action, as set forth in the letter of allowance, which was mailed on June 23rd, 1983, did not take place. (Ap. 11)

The court used only part of the referenced letter of allowance to support its conclusion, and completely ignored the indication in that document that the Examiner had examined the claims due to the citation of prior art. See id.¹⁴

In addition, the district court failed to recognize the distinction between the examination of claims in the continuation

¹⁴The Prior Art Statement of January 28, 1983 referenced several ostomy patents that had been cited in the corresponding British prosecution and had not been made of record in the parent case, thus necessitating examination. (Ap. 656-61).

case and the proofreading of claims against those in the parent file:

Based upon the evidence, there's no indication that the examiner went back and compared the language of the claims that had been represented to him as having been allowed with the language which was presented to him in the continuation application. (Ap. 11-12)

Only the following admitted speculation of Mr. Sears supports the court's conclusion:

Now, again, I must speculate to some extent. If Wallen detected the mistake with respect to old claims 50 and 51 being carried over as allowed, then he had one option. He could reject anew, 112, second paragraph -- for whatever reason the indefiniteness is still there -- or if for any reason, he changed his mind, then he should have made a statement of record here. Now, you don't find either one.

The only conclusion I can draw is that Wallen relied upon the representation. (Ap. 5222)

The first difficulty with Mr. Sears' speculation is that it is based on an assumption that on an independent reading of the claims the Examiner would have concluded they were indefinite. Secondly, Mr. Sears assumed that if the Examiner had made a comparison of claims from the original application with those in the continuation, he would either have persisted in the rejection or expressly stated that he was recanting the prior basis for rejection. Contrary to these assumptions, the prosecution history shows there were at least two independent examinations of the claims. The record of the prosecution history further establishes that Squibb disclosed prior art references on two occasions during the prosecution of the continuation application

and that the Examiner considered these disclosure statements on three occasions. See supra pp. 12-13. (Ap. 659-61, 705-06, 714-15) Furthermore, on the letter of allowability referred to by the court, the Examiner checked block 5 indicating he had considered the art cited by the Applicant. In order to have considered the art submitted by the Applicant, the Examiner had to consider all the claims pending at that time in the application, whether allowed or not in light of the new art. The Examiner could have rejected any or all of the claims on § 112 grounds or on any other basis. In fact, Mr. Michell, one of Defendant's experts on PTO practice, admitted not only that the Manual of Patent Examining Procedure provides that each application will receive an examination, (Ap. 5294) but that he personally, in his capacity as a supervisory examiner in examining a continuation application in which claims had previously been allowed, had made a § 112 rejection after reconsidering those claims in light of new art submitted by the applicant. (Ap. 5293-307, 2525-753) Mr. Michell admitted that even when a claim has been allowed in a patent application, if new art is cited in the continuation case, the examiner must look at the references and consider them with regard to all the claims. (Ap. 5310-11). Examiner Wallen had the same duty and all of the evidence leads to the conclusion that he carried out that duty.

Mr. Sears acknowledged that the Examiner had a duty to examine all the claims, and to see that all the claims were allowable. (Ap. 5263-64) Furthermore, Mr. Sears acknowledged that the Examiner had the parent file wrapper before him. (Ap. 5265-66) Mr. Sears further admitted that the prosecution history

established that in the continuation application the Examiner made a new search, and that he considered the art supplied by the Applicant. (Ap. 5226-28)

The trial court's conclusion that "but for" the misrepresentation in the preliminary amendment, Claim 9 would not have issued is further discounted because the Examiner initialed two prior art statements after the letter of allowability relied upon by the court in its decision. The Examiner considered the references cited in the Rule 312 amendment against the claims. (Ap. 5171-73, 3346-49, 5233, 705-06, 714-15)

An examiner examines claims for all aspects affecting patentability. Every application is to receive an examination under 35 U.S.C. § 131. (Ap. 5294) There is no requirement for an examiner to explain the reason for allowance, nor is it common for examiners to do so. (Ap. 5731, 3298) Examiner Wallen's own inconsistent application of § 112 relating to the "encircled" language in the claims in the parent case is indicative of a lack of conviction in the merits of the indefiniteness rejection. (Ap. 948-49; 965-67; 985; 999-1002)

Examiner Wallen initialed PTO form 1440, to indicate he had considered the art, which he could not have done without examining the claims. (Ap. 659-61, 705-06, 714-15) The trial court's finding ignores this record of examination and implies that the Examiner misrepresented that he considered the art when he initialed the forms.

II. THE DISTRICT COURT ERRED AS A MATTER OF LAW IN FINDING THAT APPLICANT'S ATTORNEY COMMITTED INEQUITABLE CONDUCT BY REPRESENTING THAT A CLAIM PRESENTED IN A PRELIMINARY AMENDMENT IN A RULE 60 CONTINUATION APPLICATION WAS ALLOWABLE AND ALLOWED, WHEN THE APPLICANT'S ATTORNEY HAD UNKNOWNLY AND MISTAKENLY INCLUDED IN THE PRELIMINARY AMENDMENT THE TEXT OF THE CLAIM WHICH CONTAINED ALLOWABLE SUBJECT MATTER BUT HAD BEEN REJECTED UNDER 35 U.S.C. § 112 FOR INDEFINITENESS RATHER THAN THE TEXT AS SUBSEQUENTLY AMENDED AND ALLOWED IN THE ORIGINAL APPLICATION, AND FURTHER, IN FINDING THAT THE ATTORNEY'S FAILURE TO CATCH THE MISTAKE CONSTITUTED GROSS NEGLIGENCE

The doctrine of inequitable conduct before the PTO has been addressed by this Court on many occasions, primarily in relation to the decision by a patentee to withhold a reference of which he had actual knowledge or the misrepresentation of test data. An intent to mislead can, under certain circumstances, be inferred from gross negligence, such as where there is evidence of the attorney's "clear awareness of the closeness of the [withheld] patent to appellant's inventions." In re Jerabek, 789 F.2d 886, 891-92, 229 U.S.P.Q. 530 (Fed. Cir. 1986). It has also been stated that intent may be proven by a showing of acts the natural consequences of which are presumably intended by the actor. Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 1151, 219 U.S.P.Q. 857 (Fed. Cir. 1983). This Court has recognized that it is often difficult to adduce direct proof of wrongful intent, and therefore an inference made from a fact established by clear and convincing evidence may suffice. Kansas Jack, 719 F.2d at 1151. Thus, where a material prior art reference is known to the applicant, but is withheld from the PTO, the fact of nondisclosure raises an inference that the attorney knew or should have known of the reference's materiality. It was in this context that the court indicated gross negligence, rather than actual

intent, can suffice. J.P. Stevens & Co., Inc. v. Lex Tex, Ltd., 747 F.2d 1553, 1560, 223 U.S.P.Q. 1089 (Fed. Cir. 1984), cert. denied, 474 U.S. 822 (1985). This inference can be rebutted by the actor, FMC v. Manitowoc Co., 835 F.2d 1411, 1415-16, 5 U.S.P.Q.2d 1112 (Fed. Cir. 1987).

However, this Court has repeatedly stated that simple negligence, oversight or an erroneous judgment made in good faith is insufficient to establish inequitable conduct. N.V. Akzo v. E. I. Du Pont de Nemours & Co., 810 F.2d 1148, 1153, 1 U.S.P.Q.2d 1704 (Fed. Cir. 1987); Reactive Metals & Alloys Corp. v. ESM, Inc., 769 F.2d 1578, 1583, 226 U.S.P.Q. 821 (Fed. Cir. 1985); Lex Tex Ltd., 747 F.2d at 1560; Atlas Powder Co. v. E.I Du Pont de Nemours & Co., 750 F.2d 1569, 1578, 224 U.S.P.Q. 409 (Fed. Cir. 1984); Hycor Corp. v. Schlueter Co., 740 F.2d 1529, 1540, 222 U.S.P.Q. 553 (Fed. Cir. 1984); Orthopedic Equipment Co. v. All Orthopedic Appliances, Inc., 707 F.2d 1376, 1383, 217 U.S.P.Q. 1281 (Fed. Cir. 1983). Even where nondisclosed information creates a complete bar to patentability, "the fact of nondisclosure (as opposed to the bar itself) would have no effect on the litigation unless there were also proof of actual wrongful intent or gross negligence in the nondisclosure." Reactive Metals, 769 F.2d at 1583 (emphasis in original). Again in FMC v. Manitowoc, the court emphasized the importance of intent as a separate and necessary element. See supra p. 18. The Manitowoc court disapproved the assertion that a holding of inequitable conduct could be based on inferences, stating that a clear and convincing standard had to be met. 835 F.2d at 1417 n.11. It is impermissible to use an inference to establish a fact, while it

is permissible to draw an inference from established facts. Id.
at 1416-17.

The difference between mistake or simple negligence on the one hand and gross negligence on the other has not been clearly defined by this Court, except perhaps in the context of the withholding of a reference known to an applicant. But the breadth of the language in such cases has been interpreted by some, including Hollister's expert Mr. Sears, to mean that there is no such thing as "simple" negligence with respect to an inequitable conduct case. Mr. Sears testified, in contravention to the Court of Appeals for the Federal Circuit's opinions cited supra p. 37, that simple negligence is enough:

Now, the Federal Circuit, in various opinions, has said gross negligence may suffice where the materiality is very high. It can't be simple negligence. And then, by way of example, the Court states, well, in the context of withholding material information, which is the more usual context nowadays, the Court says, "Well, if a reasonable attorney should have known that, say, a withheld reference was material, that's gross negligence." In my simple way of thinking, it sounds very much like simple negligence, rather than gross negligence. But the Court characteristically goes to the particular facts involved, a spectrum of facts, and comes to a conclusion whether gross negligence or not is present. (Ap. 5237-38) (emphasis added)

Simple negligence traditionally consists of four elements: a duty to conform to a certain standard of conduct, a failure to conform to that standard, a causal connection between the conduct and damage, and actual damage. W. Prosser, The Law of Torts (Hornbook Series) § 30 at 146 (3d ed. 1964). Gross negligence requires willful, wanton or reckless misconduct, that the actor

intentionally perform an act of unreasonable character in disregard of a known or obvious risk that harm will follow. Id. at 189.

In Machinery Corp. of America v. Gullfiber AB, this Court adopted the traditional tort concepts to define gross negligence in the context of whether a case was exceptional under § 285:

The gross negligence standard has been defined as requiring willful, wanton, or reckless misconduct, or evidence of "utter lack of all care." Prosser and Keeton, The Law of Torts, § 34 (4th Ed. 1984). Thus, conduct short of fraud, but in excess of simple negligence is sufficient for deciding that the case is "exceptional" under § 285.

Machinery Corp., 774 F.2d 467, 473, 227 U.S.P.Q. 368 (Fed. Cir. 1985).

In the instant case, the trial court inferred gross negligence from an erroneous finding of materiality as well as an improper conclusion of law that an examiner must rely on representations of the applicant, in spite of Mr. Sears' admitted uncertainty that Mr. Davis' conduct would constitute gross negligence and his further testimony that there was no deceptive intent.¹⁵ Mr. Sears incredibly concluded there was inequitable conduct according to the guidelines of the Federal Circuit. (Ap. 5237, 5279-80) With this instructional background, the trial court elevated what was a mere mistake or, at most, simple negligence into gross negligence. But Mr. Sears' equivocal testimony does not constitute clear and convincing evidence. The

¹⁵Mr. Sears relating the facts to the standard for gross negligence stated: "'--- a state of mind so reckless respecting consequences as to be equivalent of intent'. I don't know whether that can be borne out here or not. It sounds like a very high grade recklessness, wantonness almost." (Ap. 5236-37) (emphasis added)

trial court ignored the requirement that intent is a separate element that cannot be inferred from materiality alone, even if it is assumed, arguendo, that the materiality conclusion was correct.

A. The District Court Erred As A Matter Of Law When It Held That A Ministerial Error Relating To Definiteness Of Claim Language Was Gross Negligence Sufficient To Support A Finding Of Inequitable Conduct

There is no question that the preliminary amendment in the continuation case contains a mistake. There is no precedent, however, for a mistake such as this one, unnoticed for many years, to be elevated to intent. The clear reason that the mistake was unnoticed is apparent: both Squibb and Hollister representatives and attorneys who read the claim did not find it to be indefinite.

This Court has cautioned against the misapplication of legal principles:

[A] fertile source of error in patent law is the misapplication of a sound legal principle established in one case to another case in which the facts are essentially different and the principle has no application whatsoever.

In re Ruscetta, 255 F.2d 687, 689, 118 U.S.P.Q. 101 (C.C.P.A. 1958)(Rich, J.), quoted in FMC Corp. v. Manitowoc, 835 F.2d at 1417 n.12.

The trial court utilized as support for its decision a case in which there was proof of a deliberate decision to withhold a reference from the PTO. This was considered circumstantial evidence of actual intent - a deliberate act done in disregard of the consequences or gross negligence. See Lex Tex Ltd., 747 F.2d at 1564. The trial court misinterpreted the law and inferred intent from materiality alone:

That takes us really to the third element of intent to mislead. In examining that element -- and this is the element that gives me the greatest difficulty, I guess not from the standpoint of proof but from the standpoint that an experienced patent attorney could allow such conduct to take place -- the language that was rejected was highly material. At the very least, Mr. Davis was grossly negligent in not catching the error. His explanation for not catching the error, what he claimed or testified was the error, was just that: "The error occurred, and I didn't catch it."

The error could have been caught by a review of the claim language from the allowed claim 50, the amended language in the Amendment After Final, by a mere ministerial person like a paralegal just sitting down and comparing the language. That wasn't done, or at least there's no evidence that that was done. (Ap. 13)

Where the conduct in question is the withholding of a highly material reference actually known to the actor, gross negligence may be inferred if that actor "should have known" it was highly material. Lex Tex Ltd., 747 F.2d at 1564. However, this Court has not imposed the "should have known" principle to require an applicant to make objectively true arguments in construing references before an examiner. Akzo N.V. v. Int'l Trade Comm'n, 808 F.2d 1471, 1482, 1 U.S.P.Q.2d 1241 (Fed. Cir. 1986), cert. denied, 107 S.Ct. 2490 (1987). The "should have known" duty was not imposed with respect to the materiality of sales data which evidenced a § 102(b) bar, even though there was evidence that, during prosecution of the patent, the inventor was aware of advertisements and sales prior to the critical date. Reactive Metals, 769 F.2d at 1584. The acts of the patentee did not evidence either actual wrongful intent or gross negligence. See id.

The trial court in the present case equated mere mistake with gross negligence by applying the "should have known" standard to every act committed or omitted. In the court's analysis, Mr. Davis should have known not to commit the error, he should have known that the error had been committed, and he should have known the error was material.

This Court has been careful not to allow materiality alone to become the touchstone of inequitable conduct. An applicant is afforded the opportunity to explain his actions, and even to purge his misrepresentations during the pendency of the application.¹⁶ But, in the case of a ministerial error, it is likely that no explanation would ever be possible. All a practitioner can reasonably be expected to do is endeavor to present accurate documents to the PTO, not to attain perfection. Squibb took affirmative action to ensure proper preparation of the continuation case. Mr. Davis employed an experienced patent attorney to prepare the preliminary amendment and reasonably expected that that attorney would prepare it properly. (Ap. 4514, 4518, 4591) Mr. Goldenberg was much more qualified than the "mere ministerial person" suggested by the trial court to be proper to prepare the document. Failure to catch the error cannot be more than mere mistake or simple negligence.

¹⁶See Rohm & Haas Co. v. Crystal Chemical Co., 722 F.2d 1556, 1572, 220 U.S.P.Q. 289 (Fed. Cir. 1983) (application must be pending, PTO must be pointed to erroneous information, and correct information must be disclosed), cert. denied, 469 U.S. 851 (1984).

B. The District Court's Finding That The Examiner Must Rely Upon The Representations Of The Applicant In A Continuation Application Concerning The Status Of The Claims In The Parent Application Is An Error Of Law

An issued patent is presumed valid, and this presumption is based on deference due to the PTO that it has properly done its job:

When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners...whose duty it is to issue only valid patents.

American Hoist, 725 F.2d at 1359 (emphasis added).

The trial court's finding of inequitable conduct was also based in part upon its erroneous belief that an examiner must rely upon the representations of the applicant. The court stated:

[T]here has been testimony in this case that, of course, an examiner must rely upon the representations of the applicant, and I believe because of the duty of candor that's imposed by law on the applicant, has every right to rely upon the representations such as made on Defendant's Exhibits 2-43 and 2-44. I believe that the duty of candor certainly is not a lesser duty than the examiner has, and I believe is a greater duty, in light of the ex parte nature of the patent application process. I don't believe the examiner has a greater duty than the person seeking the patent. (Ap. 12, 3296-97)

The court applied the law improperly to the situation before it. In certain circumstances, an examiner must rely upon the representations of an applicant, such as where the applicant supplies test results in affidavit form, because the PTO has no independent means for conducting its own tests. In contrast, however,

an examiner has the obligation to do more than to simply rely upon the representations of the applicant with respect to items before the PTO. For example, applicants commonly represent that the claims are allowable over the references. If an examiner "must" rely on representations of the applicant, there would be no need to examine an application. While Appellants agree that an applicant should not knowingly misstate the record before the PTO, an examiner need not rely upon statements made by the applicant as to the status of the record, or as to the meaning of art before the PTO.¹⁷

This case of first impression is analogous to the situation concerning misstatements as to the meaning of a reference before the examiner. Where the alleged inequitable conduct involves the misrepresentation of facts, but the examiner has the true facts before him, materiality is lacking. Akzo, 808 F.2d at 1482 (attempt to distinguish a process from two patents which were before the examiner was not material). When the material is before the examiner, he is "free to reach his own conclusion. . . ." Id. In Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1457, 223 U.S.P.Q. 603 (Fed. Cir. 1984), the failure to advise the examiner of art in the co-pending application was not inequitable, because the same examiner was assigned the co-

¹⁷In contrast to the situation in Kangaroo U.S.A. v. Caldor, Inc., 778 F.2d 1571, 228 U.S.P.Q. 32 (Fed. Cir. 1985), where a utility patent applicant attempted to claim priority to a design patent and opined that it should not be penalized for the examiner's failure to check for priority, Appellants are not relying on evidence of failure of duty for their contentions but evidence of compliance with duty.

pending application and had a duty not to issue conflicting patents.

In the instant case, the parent file wrapper was before the Examiner. The Examiner's search notes indicated he referred to the parent file and made a new search. (Ap. 5265-66, 5226) The chart provided easy reconciliation of the claims. All the information the Examiner needed to determine the error was before him, and he had the duty to examine the claims. (Ap. 5263-64, 3296-97, 2122) There is no res judicata based on an examiner's previous rejection of claims. (Ap. 5223, 3298) An examiner can change his mind at any time. (Ap. 5211) Furthermore, the representations in the preliminary amendment were ambiguous. In the preliminary amendment the claims in the chart were referenced as both "allowed" and "allowable" and it was noted that some claims had been rewritten in independent form. There was further indication that two claims under the "allowed" column had been combined. These unartful statements invited examination.¹⁸ (Ap. 5218-19, 3297)

The record demonstrates that the Examiner examined the continuation claims and did his job.¹⁹ No rule required that he explain why he was not rejecting Claim 43 of the continuation case under § 112 even though he had rejected unamended Claim 50

¹⁸Squibb presented proper testimony that there was a difference between "allowed" and "allowable"; that "allowable" means some further action must be taken before the claim will be allowed. (Ap. 4517, 4538, 4542-45) However, Hollister's expert apparently convinced the court to the contrary. (Ap. 10, 5211)

¹⁹Sears admitted that the examiner would likely have looked at at least one claim to see if the language had been scrunched properly. (Ap. 5219)

in the parent case. (Ap. 5270-71) Only speculation and assumptions support the trial court's finding that the Examiner did not examine the claims. Proof of inequitable conduct must, however, be by clear and convincing evidence, not speculation and assumption.

Squibb is not trying to benefit from its failure to catch the error. It believes, however, that the insignificance of the mistake is evident because neither Mr. Davis, Examiner Wallen, Examiner Wallen's supervisor, nor (during years of this litigation) Hollister noticed that anything was indefinite about Claim 43 of the continuation case considered on its own, and because Claim 9 is in fact definite under 35 U.S.C. § 112.²⁰ Squibb relies on the presumption that an examiner complies with his duty to examine the claims for invalidity, on the evidence that Examiner Wallen examined the claims in this case, and on the fact that the public suffered no harm by the issuance of Claim 9.

III. THE DISTRICT COURT CLEARLY ERRED IN FINDING THAT THE CONDUCT OF APPLICANT'S ATTORNEY WAS SUFFICIENT TO CONSTITUTE AN INTENT TO MISLEAD WHEN CONSIDERED IN LIGHT OF THE NATURE OF THE ERROR AND BECAUSE THE COURT IMPROPERLY RELIED ON EVENTS OCCURRING AFTER ISSUANCE OF THE PATENT

Later intent or gross negligence cannot be used to prove that the requisite intent was present when a misrepresentation was made to the PTO. The act must either have been done with a deliberate scheme to defraud or there must be clear and convincing proof of the fact of misrepresentation "coupled with proof that the party making it had knowledge of its falsity."

²⁰plaintiffs' expert, Mr. Arnold, also did not notice the error when he reviewed the file wrapper. (Ap. 5711)

Kangaroo U.S.A. v. Caldor, Inc., 778 F.2d 1571, 1576, 228 U.S.P.Q. 32 (Fed. Cir. 1985) (quoting the district court with approval).

The conduct must not be evaluated with hindsight:

[T]hat something thought to be true when stated, or a piece of prior art thought unimportant to the PTO's decision was later determined to have been untrue or important, will not automatically and alone establish that fraud or inequitable conduct occurred. The fact finder must evaluate all of the facts and circumstances in each case.

Kansas Jack, Inc. v. Kuhn, 719 F.2d 1141, 1151, 219 U.S.P.Q. 857 (Fed. Cir. 1983) (emphasis added).

In SSIH Equipment S.A. v. Int'l Trade Comm'n, 718 F.2d 365, 218 U.S.P.Q. 678 (Fed. Cir. 1983) the appellant urged that conduct occurring after the prosecution of the patent-in-suit with respect to later allegedly interrelated patents rendered the patent-in-suit unenforceable. The court rejected the argument, stating: "The acts which are alleged to have taken place all occurred after the '762 patent issued and do not deal with the invention claimed in the '762 patent". SSIH, 718 F.2d at 378.

Even if the trial court's materiality conclusion is assumed, arguendo, to be correct, an inference of intent is improper and based upon circular reasoning. The trial court, after making its conclusory finding of materiality based on the fact that the Examiner had rejected language in unamended Claim 50, stated: "It is also clear that Mr. Davis had knowledge of that materiality of that language, since it was first rejected, and then, when amended, was properly allowed." (Ap. 13)

The evidence, however, shows that Mr. Davis did not have actual perception of the allegedly material language at the time

the continuation application was submitted to the PTO, nearly two years after the § 112 rejection had been made.²¹ In contrast to the situation in which a practitioner withholds a prior art reference, Mr. Davis' knowledge did not coincide in time to the act of withholding information from the PTO.

There is no basis in law for the trial court's conclusion that the gross negligence was "multiplied" each time Mr. Davis allegedly had an opportunity to review the claim language. (See Ap. 13-14) This conclusion, which was apparently based on Mr. Sears' testimony that the language should have "rung a bell" with Mr. Davis each time he picked up the file, required the trial court to make the erroneous assumption that there would have been a reason to look at this claim language.²²

The only later opportunity specifically identified by the trial court was "the opportunity that he had after this case was filed and it was specifically brought to his attention." (Ap. 16-17) As previously discussed, the latter event occurred in March, 1987. However, the court did not address what action it believed should have been taken. It appears no clear avenue was available.²³ As indicated in the SSIH case, events occurring after the issuance of the patent are not relevant to assessing if inequitable conduct occurred during prosecution. Therefore, the

²¹The office action was mailed on September 5, 1980. The continuation case was filed July 2, 1982.

²²The district court failed to explain, if the language did not "ring a bell" upon review before filing in July 1982, how it could do so even later in time. Mr. Davis read Claim 9 and 27 when he filed the petition to make special, but the language did not "ring a bell" at that time. (Ap. 5161)

²³See supra n.16.

allegation made by Hollister during the lawsuit in no way relates to Mr. Davis' intent at the time the error was made.

The allegedly negligent act performed in the prosecution of the patent application was wholly contained in the preliminary amendment of the continuation case. The evidence indicates that the statement made in the preliminary amendment was thought to be true when made. The evidence showed that Mr. Davis, when reviewing the case, never noticed that the unamended claim had been filed. Mr. Davis believed unamended Claim 50 was valid under § 112, that unamended and amended Claim 50 were of the same scope and that both were infringed by the Hollister device.²⁴ Therefore, no bell "rung" when he read Claim 43.²⁵ To accept the trial court's reasoning that the negligence was multiplied would be to accept that Mr. Davis had an extraordinary duty to recall the § 112 rejection made in the parent case against unamended Claim 50 years later by reading Claim 43. The trial court improperly imposed a duty on Mr. Davis to either have an infallible memory, and/or to proofread the claims against the parent case whenever he filed a new paper.

²⁴Mr. Arnold's testimony confirmed Mr. Davis' belief (Ap. 5667-71, 5706-07, 5768-75, 1303) that the scope of amended and unamended Claim 50 were the same. Squibb's lead counsel in opening statement reflected Squibb's belief: "As far as Squibb is concerned, the limitations in the amended Claim 50 can be placed in Claim 9 of the patent. It makes no difference." (Ap. 4115)

²⁵Furthermore, Mr. Davis would have been unable to discern that the PTO had been misinformed merely by reading Claim 43 since the characterization of Claim 43 in the preliminary amendment, not the presence of Claim 43, is the basis of the alleged inequitable conduct.

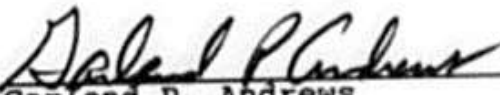
CONCLUSION

The trial court's conclusion that Appellants engaged in inequitable conduct in the procurement of the patent-in-suit eviscerates the law developed by this Circuit that requires clear and convincing proof of intent and materiality. One could hardly conceive of a clearer example of an immaterial mistake made in the course of prosecuting a patent.

Here, there was no evidence of intent to mislead the PTO. Gross negligence was improperly inferred from the court's erroneous finding of materiality. But even if materiality was present, the balancing of materiality and intent does not indicate inequitable conduct was present. If the error was more than a mere mistake, it was simple negligence, which is not enough.

For the reasons detailed above, Appellants therefore ask this Court to reverse the judgment of inequitable conduct rendered by the Northern District of Illinois.

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing "BRIEF FOR APPELLANTS" was served upon James T. FitzGibbon and Angelo J. Bufalino, Lockwood, Alex, FitzGibbon & Cummings, Three First National Plaza, Suite 1515, Chicago, Illinois 60602, Attorneys for Appellee, by Federal Express delivery service on this 24 day of April, 1988.

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