

# **Appellee's Brief**

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U. S. DISTRICT COURT OF APPEALS  
7th Circuit

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BRIEF FOR APPELLEE

FRANCIS X. GINDHART  
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In The  
United States Court of Appeals  
For the Federal Circuit

Appeal No. 88-1263

KINGSDOWN MEDICAL CONSULTANTS, LTD.  
and E.R. SQUIBB & SONS, INC.,  
*Plaintiffs-Appellants,*

v.

HOLLISTER INCORPORATED,  
*Defendant-Appellee.*

Appeal From The United States District Court For  
The Northern District of Illinois, Eastern Division,  
Honorable James F. Holderman

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CERTIFICATE OF INTEREST

The undersigned counsel of record for Hollister Incorporated (Defendant-Appellee) furnishes the following list in compliance with Rule 47.4:

- (a) Hollister Incorporated, an Illinois corporation.
- (b) Not applicable.
- (c) Not applicable.
- (d) Lockwood, Alex, FitzGibbon & Cummings  
Three First National Plaza  
Chicago, Illinois 60602  
  
Schuyler, Roche & Zwirner  
3800 Prudential Plaza  
Chicago, Illinois 60601

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.



## I. INTRODUCTION

The plaintiffs, E.R. Squibb & Sons, Inc. and Kingsdown Medical Consultants, Ltd. (collectively "Squibb") secured allowance of two independent claims (9 and 24) from the U.S. Patent and Trademark Office ("PTO") by falsely representing in a continuation application that such actually rejected claims were claims which had been allowed in the parent application. Squibb then sued the defendant, Hollister Incorporated ("Hollister") for infringing the patent thus obtained, namely U.S. Patent No. 4,440,363 ("the '363 patent").

Even after Hollister discovered this deception and advised Squibb about it, Squibb denied the deception and then later denied its materiality. Forswearing the opportunity to dedicate, disclaim or try to reissue its '363 patent, Squibb instead proceeded recklessly to trial in the district court. There Judge Holderman held the '363 patent unenforceable by reason of Squibb's inequitable conduct. He stated:

Plaintiff [Squibb] 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 '363, the patent-in-suit, would not exist today (JA 8).

Judge Holderman, concluded his opinion by deploring Squibb's conduct:

I will state that this is not an easy opinion to issue in light of what I perceived in this record. However, I believe because of the nature of patent proceedings, the complicated aspects of the technical requirements of patents, the workload in the Patent Office, that such conduct as occurred here cannot be allowed, and I believe that this type of conduct should not allow enforcement in the federal courts (JA 19).

Now, in a further display of the corporate arrogance manifested in its original and continued deceptions, Squibb has filed this appeal. Squibb's opening brief takes a scattershot approach replete with arguments which, without exception, are irrelevant or incorrect. Through these tactics Squibb intends to deflect consideration of the real issue and imply the existence or substance of a variety of matters not in issue. The real issue before this Court is whether Squibb's egregious conduct may be excused on this record.

Squibb's campaign to confuse the issue is illustrated by its disingenuous attempt to defend its high-handed substitution of rejected claims for allowed claims. For example, Squibb produced a seasoned patent attorney expert who testified that:

[claim] language tends to kind of merge together, in any event, and you do not always pick out of the claims every nuance of difference in the claim language. (JA 5710).

He even repeated this astonishing contention (JA 5712), which typifies Squibb's disregard for the distinction between the bounds of permissible advocacy and outright misstatement. Likewise, Squibb boldly argues that the rejected and allowed claims are the same. In support of its contention, Squibb presented the testimony of its in-house attorney Mr. Stephen B. Davis, its expert Mr. Tom Arnold, and arguments of its trial counsel. Each of Squibb's attempts to explain its actions stands as uncontrovertible evidence of Squibb's disrespect for the PTO and Squibb's intent to ratify its prior conduct of procuring unduly broad

claims through deceptive substitution rather than honest prosecution. Although Squibb had every opportunity to acknowledge its misrepresentations forthrightly and attempt remedial measures, Squibb brazenly continued to assert tainted claims from the '363 patent. For this reason, Squibb's efforts here are branded as the ultimate in frivolous appeals.

## II. HOLLISTER'S STATEMENT OF ISSUES PRESENTED FOR REVIEW

Hollister is mindful of Rule 28(b) of this Court which is directed to an appellee's statements of issues and of the case.

On pages 1 and 2 of its brief, Squibb lists seven issues which it contends are presented for review. All of the issues are objectionably argumentative. Specifically, issues 1, 2, 3, 4, 6, and 7 set forth propositions followed by incorrect statements of facts said to underlie such propositions; issue 5 misstates the district court's findings; and issues 1, 2, 4, 5, and 7 are also objectionable as presenting factual issues in the guise of legal issues.

Hollister submits that the following important issues were omitted:

1. Does the Duty of Candor to the Patent and Trademark Office forbid securing allowance of patent claims in a continuation application by falsely representing that such claims correspond to claims allowed in the parent application?

2. Where one or more, but less than all, of the claims of a patent are procured through inequitable conduct, is the entire patent unenforceable?

3. Where a claim is procured through misrepresentation, is it further impermissible to (a) file and maintain a lawsuit based on such claim; and (b) continue the lawsuit in the district court through this appeal after being given actual notice that defendant was aware of such conduct, on the basis that such misrepresentations were insignificant or ministerial.

### III. STATEMENT OF THE CASE

Hollister also submits that Squibb's Statement of the Case, including its Statement of Facts, is argumentative, contains extended development of irrelevant matters and ignores other important factual matters. Therefore, Hollister is also submitting its version of the Statement of the Case.

#### A. NATURE OF THE CASE

This non-jury patent case was tried before Judge James F. Holderman in September, 1987 and January, 1988. Judge Holderman held Squibb's '363 patent unenforceable for inequitable conduct, finding clear and convincing evidence that Squibb secured allowance of eight asserted claims by misleading the PTO during prosecution of the '363 patent (JA 7-8). Judge Holderman specifically found that the Examiner's 35 USC §112 rejection of unamended claim 50 (patent claim 9) was appropriate (JA 16), and that tainted claim 9 does not comply with 35 USC §112 (JA 11).

On January 25, 1988, Judge Holderman delivered his findings and conclusions (JA 6-20) and on February 12, 1988, entered the Judgment appealed from (JA 3). These findings are concise, clear, and overwhelmingly supported by the record. The conclusions represent an eminently correct application of the law.

This brief details what is overwhelmingly evident from this record, namely, that Squibb, an immense multi-national pharmaceutical company (JA 4736) and recent entrant into the ostomy device field (JA 4910-11), asserted an unenforceable patent in an attempt to exclude Hollister from the so-called two-piece ostomy appliance market.

Squibb's courses of conduct in the PTO, and in the prosecution of this lawsuit generally, have made this a truly exceptional case. Even now, before this Honorable Court, Squibb continues its impermissible conduct.

B. STATEMENT OF THE FACTS

1. Identity And Background Of Hollister

Hollister is a Chicago-area company owned by a trust established for the benefit of its employees by its founder, John Dickinson Schneider (JA 4944). Mr. Schneider dedicated his company to the concept that significant improvement in ostomy patient care could be made by developing new ostomy products through research and development (JA 4904). Hollister led ostomy

care out of the "dark ages" and into its present era, wherein safe, sanitary, convenient, low visibility throw-away products affording outstanding reliability and physical and psychological comfort are available to cancer patients or others unfortunate enough to require ostomy care (JA 4908). Hollister markets a broad range of appliances using its proprietary leak-proof, odor-free disposable plastic bags, removably affixed to the body in a variety of ways (JA 4903).

Some 20 years ago, Hollister perceived the need for improved ostomy care outside the United States, and expanded its successful operations into the British Isles and a major portion of Europe. Its products are marketed in Europe and elsewhere through Abbott Laboratories (JA 4905-06).

2. Squibb's Identity And Its Entry Into The Ostomy Field

Squibb is a hugh international pharmaceutical company which did not enter the ostomy business until the late 1970's (JA 4736, 4910-11). In about 1976, Messrs. Peter Steer and John Edwards teamed with a former Hollister/Abbott representative, Howard Matthews, to found the co-plaintiff, Kingsdown Medical Consultants, in England (JA 4350, 4357). Matthews was intimately familiar with the highly confidential sales, marketing, and financial plans of Hollister (JA 4936-37, 4944-45). Using information gleaned from Matthews, Steer persuaded Squibb that entering the ostomy business would be financially profitable for

Squibb (JA 1338-42, 4939, 4942-47), which was not then active in the ostomy field (JA 4910-11).

Steer advised Squibb that a bag made from the highly successful Hollister specialty plastic film could be combined with Squibb's existing "Stomahesive" dressing to provide a successful ostomy appliance (JA 1338-42). Once Kingsdown received Squibb's financial backing, Steer made prototypes of a two-piece unit (JA 4360) which Kingsdown later referred to as using the "Tupperware" principle to removably affix the bag to the dressing (JA 3907, 3913, 3916, 3919). Squibb filed patent applications immediately in the U.K. (JA 4437-38). These U.K. applications were later combined and filed here in the U.S. as a single application. Squibb began marketing its products in the U.K. (JA 4911, 4380), and introduced them into the U.S. in 1978 (JA 4667). The mammoth size of Squibb's organization and its extensive hospital contacts positioned Squibb to achieve immediate widespread distribution and sales of its two-piece product (JA 4759).

### 3. The Development of Hollister's Two-Piece Product

Over the years, Hollister, the acknowledged world leader in ostomy care, offered a variety of one-piece ostomy appliances and at least one two-piece appliance, referred to as the "loop ostomy" product (JA 4913). The loop ostomy product, like the later Squibb two-piece product, featured an adhesive pad or dressing component with a semi-rigid plastic coupling ring affixed to its surface,

and a bag component with a second coupling ring secured around the perimeter of the bag opening. The bag ring of the loop ostomy product includes an adhesive that permits the bag to be removed and replaced without removing the pad or dressing from the patient. Contrary to the false statement of Squibb's witness (JA 4266), this product is commonly used on both ambulatory and bed-ridden patients (JA 4017, 4913). Although Steer denied knowing of this Hollister product (JA 4449), Steer's partner Matthews was intimately familiar with Hollister's loop ostomy product long before Steer conceived his product (JA 4936).

In 1981, Hollister decided to develop and manufacture its own mechanically two-piece coupled ostomy product (JA 4959). Hollister had studied Tupperware and other similar snap-on plastic cap and closure fastening arrangements such as those used by Squibb (JA 5074-76). Hollister, however, wished to make a better two-piece product which did not have the significant drawbacks of the Squibb product (JA 5067-77, 4922-25). Hollister overcame these problems developing an invention of its own -- its "floating flange" product. In the Hollister construction, unlike Squibb's, the coupling ring does not directly overlie and flex with the dressing. Instead, the coupling rings "float", i.e. they are spaced apart from the dressing by means of a flexible web of plastic material (JA 3981-88, 4929, 5079-81). This construction permits the user to position his fingers between one coupling ring and the dressing to help snap the rings together, and confirm by feel that they are securely coupled. Equally or more important,



it permits the coupling rings to float or be isolated from the bending stresses and distortion which occur in Squibb's product when the inner coupling ring is flexed excessively. This occurs in Squibb's product when the dressing moves with the patient's body (JA 3981-88, 5080-81). Hollister's product is a patentable improvement (See JA 3981-99) over prior two-piece appliances, including both Hollister's earliest developments and Squibb's two-piece product.

#### 4. The Prosecution History of The '363 Patent

Squibb filed its parent application in 1978. Several official actions and responses followed. By 1980, the Examiner had rejected independent claims 50 and 51 (i.e., patent claims 9 and 24) in the parent application for failure to comply with 35 USC §112. The Examiner held that the claim language, specifically the use of the word "encircled," was at odds with the drawing and was ambiguous and indefinite (JA 3517).

Squibb did not dispute the Examiner's rejection of independent claims 50 and 51. Rather, its attorney, Davis, acknowledged the Examiner's position and acquiesced in the rejection and voluntarily amended the claims to overcome the rejection (JA 3520-28). In this amendment, Davis defined the coupling ring as "encircling the intersection of said aperture and said pad or dressing surface" (JA 3521). In his remarks, Davis said that the amended claims are now in compliance with 35 USC §112 (JA 3524). In this exchange, the precise meaning of the term

"encircled", as used in these claims, was agreed upon and became controlling for purposes of interpreting these claims. After Squibb amended claims 50 and 51, they were allowed (JA 3529); Squibb appealed the rejection of other claims to the PTO Board of Appeals (JA 3530).

After Squibb filed its PTO Appeal, but before the decision on appeal, Squibb became aware of and studied Hollister's newly introduced "floating flange" product (JA 9-10, 4475). Squibb then made a decision to file a Rule 60 continuation and drop the appeal (JA 3543-45). Squibb filed a preliminary amendment in the continuation application. Squibb submitted claims 50 and 51 in their original, rejected form as continuation claims 43 and 58. In connection with this amendment, Davis signed and forwarded a paper stating several times that these claims were the amended claims that had been allowed in the parent case (JA 3290-97). In fact, the claims presented did not contain the amendatory language that had been agreed upon with the Examiner as being a condition of their allowance.

As prosecution of the continuation application proceeded, Squibb continued to make express representations to the PTO that these rejected claims had been allowed or indicated allowable during prosecution of the original application. Specifically, such misrepresentations were made Squibb in: (a) the petition to make special (JA 3331-32); and (b) the declaration in support of the petition to make special (JA 3334-35). Squibb later amended

these claims (then claims 43 and 58) among others, under Rule 312 while maintaining without change the previously rejected claim language (JA 3351-55).

When the '363 patent issued, the claims in whose rejection Squibb had acquiesced became claims 9 and 24; claims 10-23 depended on claim 9.

#### 5. Procedural History of This Action

Hollister introduced its two-piece product in early 1982 (JA 4931). After Squibb studied Hollister's product, Squibb threatened Hollister with an infringement suit (JA 4015). The day the '363 patent issued, July 17, 1984, Squibb sued Hollister.

Although Squibb's conduct did not cause Hollister to incur significant expenses at the time Squibb was making its material misrepresentations to the PTO, Hollister has since incurred extreme expense and inconvenience in defending against Squibb's charges. Squibb not only filed its action, but also maintained it even after it knew that Hollister had detected the improper claim substitution.

Hollister set forth the facts surrounding its discovery of Squibb's conduct in an Amended Answer and Counterclaim (JA 256-57). Squibb responded to Hollister's charge by asserting that Hollister should have discovered the substitution earlier and by falsely asserting that the charge was based only on Hollister's

misunderstanding of the words "allowed" and "allowable" (JA 226-27, 229-30). In its trial brief, its proposed Findings and Conclusions and even in its opening statements, Squibb continued to try to mislead Judge Holderman as to the nature of Hollister's charges.

Squibb was fully aware of various steps it could have taken in the PTO regarding claims 9 and 24 (JA 4600-04). It was also presumably aware of 35 USC §288. Each of these options was available to a patentee who was not guilty of deceptive intent. Squibb nevertheless continued to assert its posture of rectitude and never demonstrated any willingness to forego this litigation or dismiss it pending attempts to have the '363 patent reissued.

#### IV. SUMMARY OF ARGUMENT

Squibb obtained allowance of two independent claims, 9 and 24 of the '363 patent, by presenting these claims in a continuation application, and falsely representing that these claims had in fact been allowed in the parent application. Claim 9 and seven claims dependent thereon were asserted in this litigation.

Far from making clearly erroneous factual determinations or improperly applying the law, Judge Holderman scrupulously heard and considered in detail all the evidence proffered by both sides. His findings are overwhelmingly supported by the record and he correctly applied the law controlling in this Circuit.

Squibb's attempts to defend its conduct simply ignore the record or constitute various facets of an assertion that the Duty of Candor set forth in 37 CFR 1.56(a) is not applicable to Squibb and that Squibb, not the PTO, is the arbiter of patentability.

## V. ARGUMENT

### A. STANDARD OF REVIEW

With respect to Judge Holderman's factual findings, this Court cannot reverse or vacate the decision of the district court unless the findings are shown to be clearly erroneous. Rule 52(a), Fed.R. Civ.P.; Underwater Devices Incorporated v. Morrison-Knudsen Company, 717 F.2d 1380, 1389, 219 USPQ 569, 576 (Fed. Cir. 1983); Orthopedic Equipment Company, Inc. v. All Orthopedic Appliances, Inc., 707 F.2d 1376, 1384, 217 USPQ 1281, 1287 (Fed. Cir. 1983). Squibb has utterly failed to make any such showing on appeal as to any finding made by Judge Holderman.

This Court has ruled that both intent and materiality as they pertain to the question of inequitable conduct, are issues of fact. American Hoist & Derrick Co. v. Sowa & Sons, 725 F.2d 1350, 1363, 220 USPQ 763, 773 (Fed. Cir. 1984) ("...the pertinency of the withheld information ... is a question of fact."); Kangaroo U.S.A. Inc. v. Caldor, Inc., 778 F.2d 1571, 1573, 228 USPQ 32, 33 (Fed. Cir. 1985) ("Good faith, intent to deceive, scienter, honest mistake are all questions of fact.").

Moreover, the fact finder "...may find intent to have been shown by any relevant degree of proof - from inference to direct

evidence, i.e., from gross negligence or recklessness to a deliberate scheming." American Hoist & Derrick Co., supra, 725 F.2d at 1363, 220 USPQ at 773.

Judge Holderman's factual findings underlying his holding that Squibb was guilty of inequitable conduct are all undeniably based on established facts appearing in the record. Squibb simply disagrees with Judge Holderman's refusal to accept Squibb's various excuses and its attempts to minimize the gravity of its own inequitable conduct. However, this in no way contradicts the fact that Judge Holderman's findings are clear, overwhelmingly supported, and consistent with the legal precedents established and adhered to by this Court.

**B. HOLLISTER ESTABLISHED EVERY ELEMENT OF ITS INEQUITABLE CONDUCT CASE BY CLEAR AND CONVINCING EVIDENCE.**

**1. Misrepresentation, Materiality and Knowledge Are Undeniably Disclosed In The Prosecution History of the '363 Patent.**

Judge Holderman relied heavily on the incontrovertible evidence contained in the prosecution histories of the parent (JA 3374-3560) and the continuation (JA 3254-3373) applications that formed the basis for the '363 patent. Judge Holderman followed the testimony of the witnesses with extreme care, observing and often commenting on or questioning each and every one of the numerous changes, amendments, submissions, and other papers which comprise these file histories. Beyond question, the prosecution

histories disclose the key landmarks of Squibb's misconduct.

Upon its initial filing, the parent application contained 34 claims. Following an official action issued on March 26, 1979, Squibb withdrew some claims from consideration and the remainder were rejected (JA 3465-88). Squibb filed an amendment on July 25, 1979, making no substantive claim changes (JA 3473-79). Squibb filed a supplemental amendment dated August 31, 1979 (JA 3480-82) adding new claims 35-40. On November 5, 1979, another official action issued, rejecting claims 1-18, 24, 25, 31, 35-40 (JA 3484-86). The Examiner indicated that claims 6-11 and 13-15 would be allowed if rewritten. Squibb never rewrote those claims. On January 17, 1980, Squibb forwarded another amendment, adding claims 41-49 (JA 3488-96).

On May 5, 1980, the Examiner issued a final action rejecting all claims but again provisionally indicating claims 6-11 and 16-18 [sic] as being allowable if rewritten (JA 3499-3502). On July 29, 1980, Davis prepared an amendment after final, cancelling numerous claims, amending claim 42 and adding claims 50-54, inclusive (JA 3506-3515).

On September 5, 1980, the Examiner issued a further official action. In this action, the Examiner rejected claims 50 and 51, among others, under 35 USC §112 (JA 3516-18).

On November 26, 1980, Davis prepared and filed another amendment after final, amending claims 50 and 51 so as to overcome the rejection under 35 USC 112 (JA 3519-28). Davis unambiguously stated:

Claim 42 has been rewritten as Claim 55 and Claims 50, 51 and 53 have been amended (Claim 54 has been cancelled) to recite that the coupling member encircles the intersection of the pad aperture and outer pad surface. Applicants submit that such language accurately defines the appliance structure as shown in the drawings and that these claims are now in full compliance with the requirements of 35 USC §112. [Emphasis supplied] (JA 3520).

This Amendment is not evidence of disagreement with the Examiner's position. It is not a predicate for a contention that the changes were immaterial or unimportant. Squibb is estopped to assert that it disagreed with the Examiner's position. This is an admission flatly contradicting the trial testimony of Davis and Squibb's expert and the statements of Squibb's trial counsel, that the scope of claims 50 and 51 was not changed.

At the same time Squibb amended claims 50 and 51, it also presented another claim (which became patent claim 27) which included the language concerning "encircling the intersection of said aperture, ...." (JA 3523). This critical language appears in non-infringed claim 27 of the '363 patent, but is absent from asserted claim 9 and unasserted claim 24 in the '363 patent.



Based on these amendments, the Examiner allowed claims 50 and 51 and claims dependent thereon (JA 3529). Several other claims were still rejected. Subsequently, a Notice of Appeal was filed as to the rejected claims (JA 3530) and the Appeal was briefed (JA 3532-42).

Hollister introduced its new floating flange two-piece product in 1982. After examining Hollister's product, Squibb filed a Rule 60 continuation application, together with a Preliminary Amendment, on July 2, 1982 (JA 3290-97). Squibb then abandoned its appeal.

It was this preliminary amendment which contained, on pages 7 and 8, the factually false and misleading statements forming the major basis of Squibb's inequitable conduct (JA 3296-97). Specifically, the preliminary amendment states:

... 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 a 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
* * * * * [Emphasis supplied] (JA 3296-97)	

The PTO issued a Letter of Allowance on June 23, 1983, indicating that these claims were "allowed in view of" the preliminary amendment (JA 3298).

Squibb subsequently filed a Petition to Make Special supported by a Declaration and additional documentary material (JA 3331-35). Although Steer admitted that he personally had no involvement in prosecuting either application (JA 4437-38), Davis procured Steer's signature on the Supplemental Declaration dated August 17, 1983, in which Steer acknowledge his Duty of Candor under 37 CFR 1.56 (JA 3336-7). Steer's participation was limited merely to his execution of a paper prepared by Davis.

Later, Squibb filed an amendment under Rule 312 wherein it made changes in the introductory language of twenty-one of the twenty-nine claims, including original claims 50 and 51 (JA 3351-55). Claim language referring to the invention as "A coupling for" was changed to refer to the invention as "An ostomy appliance (JA 3341-42). Even though Squibb changed the introductory language of both claims 50 and 51, Squibb did not give notice to the PTO that the claim language had been previously changed from its amended form back to its rejected form. Finally, in the Rule 312 amendment Squibb added a new Fig. 11 with the following remarks:

Thus it is submitted that this new figure does not involve new matter and that the entry assures compliance with MPEP 608.01(1), 608.02(e), 706.03(n), and 37 CFR 1.117 since allowed claims 43-63 are directed to the two-piece appliance. (JA 3343).

Judge Holderman scrupulously followed the testimony of the witnesses, including Davis, Sears, Lucas, Lungmus and Arnold, as they reviewed the prosecution history. One such witness was Jere W. Sears, a former deputy solicitor of the PTO. The clear, but non-adversarial nature of his testimony underscored his objectivity. No matter what Squibb may say, the prosecution history unquestionably shows sufficient evidentiary basis for Judge Holderman's findings of misrepresentation, materiality, and knowledge. Squibb made false statements of fact and the Examiner relied on these false statements of fact in allowing the claims.

The Examiner's 112 rejection of original claims 50 and 51 and the explicit acknowledgement and acquiescence in that rejection by Davis, are hard, uncontradictable facts which Squibb simply cannot sweep away. Judge Holderman's opinion properly relies heavily on these facts. Their evidentiary weight is not merely "clear and convincing," it is undeniable and overwhelming. Yet Squibb pretends this evidence does not exist.

2. Squibb's Witness Davis Admitted Misrepresentation, Knowledge, and Materiality Of The Status Of Claims 50 and 51

Davis explicitly admitted that Squibb had misrepresented the status of original claims 50 and 51 (JA 4516-17). He could not say otherwise in the face of the prosecution history. Davis tried

to justify this action by stating that, in certain instances, his representations to the PTO were reflections of his subjective opinion that the claims were "allowable" (JA 4662). The record is clear, however, that there was really no difference between the meaning of "allowed" and "allowable". Even Davis admitted there is no practical difference between these terms and that these terms were used interchangeably by the PTO (JA 4518) and by Davis himself (JA 4545). Sears also testified that there was no difference between the meaning of these terms (JA 5245). Judge Holderman agreed (JA 10).

Although Davis stated that the Preliminary Amendment was actually prepared by a Mr. Goldenberg, a Chicago practitioner, Davis admitted that he himself reviewed and signed the Preliminary Amendment incorporating the misrepresentation that Squibb was presenting allowed rather than rejected claims (JA 4515, 4518).

Goldenberg, the putative author of the preliminary amendment, was not called by Squibb to testify (JA 16).

Davis' own admissions thus established that Squibb substituted the original rejected claims for claims which had been allowed only after being amended. This unquestionably establishes that the differences were material in securing allowance of the claims, and that Squibb had knowledge of these differences, exactly as Judge Holderman found (JA 13). Only at trial did

Squibb assert that these differences had somehow become immaterial.

Davis admitted that he was the author of the Petition To Make Special, and that in order to make the statements in the Petition, he had personally compared the Hollister "floating flange" product to the '363 patent claims (JA 5157).

Finally, Davis admitted that he was aware that the remedies of disclaimer, dedication, and reissue were available to any patentee who believed that its inoperative or invalid patent could be salvaged by revision, amendment, or like action (JA 4600-04). He did not explain why Squibb continued full speed ahead with its action against Hollister instead of telling its latter-day story of purported innocence to the PTO, where the misrepresentation occurred. Squibb, of course, needed the broader, rejected language of claim 9 to make out a plausible infringement case.

There can be no doubt that Squibb's misrepresentation, its materiality, and Squibb's knowledge of its materiality were established through an abundance of clear and convincing evidence.

3. **Judge Holderman Found  
Squibb's Gross Negligence Was  
Multiplied When Davis Presented  
His Petition To Make Special**

The preliminary amendment containing Squibb's representation that claims 43 and 58 corresponded to allowed claims 50 and 51 in

the parent application was filed on July 2, 1982. Several months later, Davis prepared a Petition to Make Special on the grounds that Hollister, a potential infinger, had entered the marketplace.

Davis prepared the declaration Squibb was required to file with its Petition to Make Special, stating that the claims in the application were allowable and would be infringed. Davis' declaration stated that he had compared the claims of the application to the Hollister product and concluded that there was infringement.

At trial, Davis testified that he reviewed each independent claim in the application and compared each independent claim to the accused construction, prior to preparing his declaration (JA 5157). The independent claims in the patent are 1, 9, 24 and 27. Although tainted claims 9 and 24 then omitted the amendatory language which had been added by the November 26, 1980 amendment, claim 27 did include the amendatory language. Sears testified that when Davis thus reviewed the four independent claims for the Petition to Make Special, the absence from claims 9 and 24 and the presence in claim 27 of the amendatory language he had personally authored should have "rung a bell" with Davis (JA 5229).

Davis was an experienced patent attorney, who was then making the key decision forcing Hollister to defend multi-million dollar litigation. Under these circumstances, any competent patent attorney would have noticed these critical differences.

Judge Holderman said:

Mr. Davis had several opportunities to review that claim language, and with each opportunity his gross negligence was multiplied (JA 13-14).

In an effort to demonstrate that Davis' conduct did not amount to gross negligence, Squibb elicited testimony from Arnold that, in making the declaration with the Petition to Make Special, Davis only had to read one claim of the patent and, hence, Sears' "ring the bell theory" had no applicability (JA 5713).

Judge Holderman refused to accept Arnold's statement. Judge Holderman pointed out to Arnold that Davis had, in fact, testified at trial that he had reviewed each of the independent claims in connection with the Petition to Make Special (JA 5713). So much for the credibility of Arnold, Squibb's expert.

**4. Hollister's Witnesses, The Documents and  
The Physical Evidence Established  
That Squibb Possessed A Strong  
Motive To Deceive The Patent Office**

Hollister's witnesses explained in detail how Hollister's floating flange product was constructed and how it operated. Squibb had threatened Hollister with infringement litigation long before Squibb's '363 patent issued, establishing the competitive posture of the parties beyond doubt. Squibb's motivation to exclude Hollister from the marketplace was also made explicit through bringing and maintaining the instant lawsuit.

Hollister's patent attorney witnesses, including Sears, Lucas, and Lungmus, had experience aggregating in excess of one hundred years. They all testified unequivocally that in Hollister's floating flange product, there was no "encircling the intersection of said aperture and said outer pad or dressing surface" by the coupling ring (JA 4245-46, 5637, 3955-60). Contrary to Squibb's assertion at p. 23 of its brief, Lungmus did not admit that amended claim 50 would cover the Hollister structure. Rather, his letter of January 26, 1984 pointed out a distinction between this claim and the Hollister product, namely, the web that spaced the coupling ring from the pad. This is clearly set forth in Lungmus' letter. Thus, Hollister's product would not infringe any claims containing that agreed-upon language. Claim 27 contains this limiting language and, Judge Holderman found, but for the misrepresentations of Squibb, this language would likewise have limited claim 9. Because Squibb simply could not keep Hollister out of the two-piece business with claims having the amendatory language, it needed the language of rejected claim 50 to cover Hollister products.

Unfortunately for Squibb, it had long since agreed to the amendatory claim language which limited its right to assert infringement. The amendatory claim language that clearly, definitely and uniquely placed the coupling ring in a position coplanar with the pad front surface is, in effect, a definition which is the "law of the case" for the '363 patent, and this action. No amount of argument can now change this fact. Whether competitive pressures or other considerations induced this misconduct is immaterial.



Of course, Squibb could have disagreed with the Examiner's position and re-presented claims 50 and 51 without amendment. Because the Examiner's position was correct, this would no doubt have precluded rather than secured allowance. Squibb therefore did not disagree. Instead, Squibb took one route in the Patent and Trademark Office, and an opposite route against Hollister.

There is overwhelming - not merely clear and convincing - evidence of Squibb's motivation to deceive, and to maintain and cover up the deception it worked on the Examiner. Its intent to do so is equally clear.

5. Judge Holderman Was Entitled To And Did Consider Squibb's Overall Course of Conduct In Determining That Evidence Of Deceptive Intent Was Present

Contrary to Squibb's repeated assertions, evidence of deceptive intent is virtually always determined by indirect, circumstantial evidence. In this case, the intent is simply one of covering up an unquestioned initial deception, followed by a series of repeated instances of improperly asserting allowed status for a rejected claim. Squibb's argument on pp. 46-47 of its Brief and its citation of S.S.I.H. Equipment, S.A. v. International Trade Commission, 713 F.2d 365, 218 USPQ 678 (Fed. Cir. 1983), is in itself an objectionable tactic. There Squibb states that it is improper to consider acts occurring after a misrepresentation as bearing on intent at the time of the act. S.S.I.H. Equipment, supra, does not stand for any such

proposition. That case simply held that misconduct applicable to two patents but not applicable to a third patent would not, per se, render the third patent unenforceable.

The case of Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 219 USPQ 857 (Fed. Cir. 1983), also does not stand for the proposition for which it was cited. As a statement of the law, Kansas Jack, supra, actually supports Hollister's position. This Court there held that fraudulent intent could not be imputed to a patentee's statement based solely on the fact that it could subsequently be established that the statements were not universally or ordinarily true. In other words, misstatements standing by themselves do not conclusively imply fraud. Hollister agrees.

However, in Kansas Jack, 719 F.2d at 1151, 219 USPQ at 861, this Court noted in language very pertinent here that:

... The intent element of fraud, however, may be proven by a showing of acts the natural consequences of which are presumably intended by the actor. Statements made with gross negligence as to their truth may establish such intent. Norton, 433 F.2d 795-796 ...

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... The duty of candor owed the PTO being uncompromising, it would deal a deathblow to that duty if direct proof of wrongful intent were required ... [Emphasis supplied].

Although this Court found the patentee in Kansas Jack lacked deceptive intent, the Court did state:

... Where one who knew, or should have known, that a piece of prior art, or other information would be material, i.e., important to the PTO in making its decision, a failure to disclose that art or information can be sufficient proof that a wrongful intent existed to mislead the PTO and may

result in a finding of what has come to be called 'fraud' on the PTO. Kansas Jack, supra, 719 F.2d at 1152, 219 USPQ 862.

In Kansas Jack, supra, Judge Rich of this Court espoused the position that the attorney's ignorance of a reference did not excuse the patentee from his obligation to disclose the reference. Squibb's deception here was committed by an attorney bound by Rule 1.56(a).

In the instant case, Judge Holderman's opinion is based on a supporting record which is replete with evidence of Squibb's misstatements, Squibb's knowledge of their materiality, their importance to initiating and maintaining this action. Judge Holderman therefore properly concluded that the existence of misstatements in securing the claims, the importance of the changes in the claims as respects Hollister's devices, and Squibb's continuing to assert tainted claims in this action, constitute clear and convincing evidence of deceptive intent. Certainly, the excuses, explanations and denials proffered by Squibb are intrinsically incredible. The evidence of Squibb's misconduct is not only clear and convincing, but also it is substantially undisputed. Squibb's argument that the difference in claim language is not important is tantamount to an assertion that it is free to bypass the PTO Examiner and make patentability judgments for itself.

From the foregoing, it can be seen that the fact and the materiality of Squibb's misrepresentations, the PTO's reliance on those misrepresentations, the PTO's issuance of rejected claims, and Squibb's assertion of rejected claim as the basis for an infringement action, followed by filing maintaining this action, all constitute clear and convincing proof of the elements of inequitable conduct. Lest Squibb forget, tainted claim 9 was also the claim Squibb chose to read on its own device in support of its commercial success argument. Squibb's evidence consists entirely of the subjective denials and speculations of the perpetrator and Squibb's rebuttal expert witness. Such denials are legally unavailing, See FMC Corp. v. Manitowoc Co., Inc., 835 F.2d 1411, 1416, 5 USPQ 2d 1112, 1116 (Fed. Cir. 1987).

6. Judge Holderman's Opinion Accords Entirely With The Law Of Inequitable Conduct

The law concerning inequitable conduct has been defined and honed by this Court in recent years. Judge Holderman was keenly aware of legal standards prevailing in this Court, and properly applied them in this case. In J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc., 747 F.2d 1553, 223 USPQ 1089, (Fed. Cir. 1984), this Court stated that inequitable conduct is broader than the "common law fraud" defined in Norton v. Curtiss, 433 F.2d 779, 167 USPQ 532 (CCPA 1970). This Court more specifically held that inequitable conduct:

...encompasses affirmative acts of commission, e.g., submission of false information, as well as omission, e.g., failure to disclose material information. (Lex Tex, supra, 747 F.2d at 1559, 223 USPQ at 1092) [Emphasis supplied].

This case, of course, involves an act of commission, that is, an affirmative misrepresentation that claims 50 and 51 as submitted in the Preliminary Amendment were allowed claims, rather than rejected claims, which was actually the case.

Addressing the issue of materiality of the misrepresentation, this Court wrote that inequitable conduct:

... requires proof of clear and convincing evidence of a threshold degree of materiality of the non-disclosed or false information. (Lex Tex, supra, 747 F.2d at 1559, 223 USPQ at 1092)

This Court established four tests, under any one of which the requisite threshold degree of materiality can be found, as follows:

(1) objective 'but for'; (2) subjective 'but for'; (3) 'but it may have been'; and (4) PTO Rule 1.56(a). i.e., whether there is a substantial likelihood that a reasonable examiner would have considered the omitted reference or false information important in deciding whether to allow the application to issue as a patent. American Hoist, 725 F.2d at 1362, 220 USPQ at 772-73. (Lex Tex, supra, 747 F.2d at 1559, 223 USPQ at 1092)

With reference to the above-mentioned Duty of Candor under 37 CFR 1.56(a) this Court announced, in a statement of controlling importance in this case:

The PTO standard is the appropriate starting point because it is the broadest and because it most closely aligns with how one ought to conduct business with the PTO. American Hoist, 725 F.2d at 1363, 220 USPQ at 773. (Lex Tex, supra, 747 F.2d at 1559, 223 at 1092).

Unquestionably, this Court adheres to its holding in Kansas Jack, that the Duty of Candor under 37 CFR 1.56(a) is measured by an "uncompromising standard". Kansas Jack, supra, 719 F.2d at 1151, 21 USPQ at 861.

This Court continues its elaboration of the type of evidence needed to find improper conduct by stating:

'Inequitable conduct' also requires proof of a threshold intent. That intent need not be proven with direct evidence. Hycor, 740 F.2d at 1540, 222 USPQ at 561. It may be proven by showing acts the natural consequences of which are presumably intended by the actor. American Hoist, 725 F.2d at 1363, 220 USPQ at 773; Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 1151, 219 USPQ 857,862 (Fed. Cir. 1983). Proof of deliberate scheming is not needed; gross negligence is sufficient. Hycor, 740 F.2d at 1540, 222 USPQ at 561. Gross negligence is present when the actor, judged as a reasonable person in his position, should have known of the materiality of a withheld reference. Driscoll v. Cebalo, 731 F.2d at 885, 221 USPQ at 751; Kansas Jack, Inc. v. Kuhn, 719 F.2d at 1152, 219 USPQ at 862.

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Once the thresholds of materiality and intent are established, the court must balance them and determine as a matter of law whether the scales tilt to a conclusion that inequitable conduct occurred. American Hoist, 725 F.2d at 1364, 220 USPQ at 774. (Lex Tex, supra, 747 F.2d at 1560, 223 USPQ at 1093).

In this case, on the issues of materiality and knowledge, Judge Holderman stated:

... There is no question that the language which was rejected by the examiner when the claim was claim 50 in the original application and the language which was allowed by the examiner in claim 50 when there was submitted by the plaintiff the Amendment After Final proves that the language was material to the issuance of the patent.

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." (JA 12-13).

Because Squibb misrepresented the status of claims 50 and 51 to the PTO -- especially after acknowledging and acquiescing in the Examiner's position, Squibb could not dispute the materiality of the language change to the issuance of the claims.

On the issue of intent, Judge Holderman stated:

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 the 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.'

\* \* \* \* \*

By failing to catch the previously rejected language, the misrepresentation to the examiner in the continuation application found its way all the way into the issued patent (JA 13-14).

\* \* \* \* \*

... I believe that there is evidence of intent to mislead, because of the, as I stated, multiple times that Mr. Davis had to correct what he testified was an error." (JA 17).

The intent finding was derived from evidence that (a) the misrepresentation was the key to obtaining allowance of two of the four independent claims of the patent, (b) these claims were reviewed in detail by Davis, as attested to in his declaration in the Petition To Make Special, and (c) this action has been continued by Squibb asserting at least one such independent claim. In the face of that evidence, Judge Holderman did not and could not believe Squibb's subsequent assertions of subjective good faith.

As this Court has stated:

... yet, a patentee facing a high level of materiality and clear proof that he knew or should have known of that materiality, can expect to find it difficult to establish 'subjective good faith' sufficient to prevent the drawing of an inference of intent to mislead. A mere denial of intent to mislead (which would defeat every effort to establish inequitable conduct) will not suffice in such circumstances. FMC Corp. v. Manitowoc, Co., Inc., 835 F.2d 1411, 1415, 5 USPQ 2d 1112, 1116 (Fed. Cir. 1987).

As this Court also held, in Kangaroo U.S.A., Inc. v. Caldor, Inc., 778 F.2d 1571, 228 USPQ 32 (Fed. Cir. 1985) good faith, intent to deceive, scienter, and honest mistake are all questions of fact.

In Kangaroo, supra, 778 F.2d at 1573, 228 USPQ at 33, this Court stated:

Intent to deceive is also a material factor in the determination of 'inequitable conduct' before the PTO, as this doctrine has evolved to enforce the high standards of conduct required of patent practitioners. As discussed in American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1363, 220 USPQ 763, 773 (Fed. Cir.), cert. denied, ---- U.S. ----, 105 S.Ct. 95, 83 L.Ed.2d 41, 224 USPQ 520 (1984), the more material the misrepresentation before the PTO, the lower the burden of proving intent. However, intent remains a factor to be weighed in meeting the burden of proving inequitable conduct by clear and convincing evidence, and evidence on the factual question of intent can not be refused consideration.

Judge Holderman held that in view of the many times Squibb had an opportunity and/or duty to review the claims in detail, and because these misrepresentations were extended and material, Squibb could easily have detected them by the exercise of a ministerial function (JA 13).

Judge Holderman very properly inferred the presence of deceptive intent both from the repeated nature of Squibb's omissions, and also from the unmistakable sequence of events. These included (1) Squibb's desire to sue Hollister, (2) its awareness that it had seriously compromised its ability to sue by its prior voluntary claim amendment, (3) its determination that



new claims would be necessary for this purpose, (4) its substitution of rejected claims for allowed claims together with a statement misrepresenting the status of these claim, (5) its repeated reference to the rejected claims as allowed claims and (6) the ease with which the misconduct could have been discovered, had it really been a mistake. Under these circumstances, Judge Holderman properly concluded that Squibb must have been aware of its own improper activities. Its continued arguments reinforce rather than cast doubt on this conclusion.

Judge Holderman's conclusion finds further support in the fact Squibb did not take remedial action even when confronted directly by Hollister. Instead, Squibb first denied the existence of the "error", then denied its materiality, denied any responsibility for the misrepresentation, and finally, when forced to admit responsibility, denied that its conduct had any impact on the propriety of Squibb's charges. This entire course of conduct unquestionably establishes that Squibb carried out the misrepresentation pursuant to a wrongful intent.

Squibb's conduct at trial, including Arnold's abortive attempt to contradict Davis' own admission that he had reviewed all four independent claims in connection with the Petition To Make Special, strongly validate Judge Holderman's findings and, Hollister submits, render this appeal frivolous.

Where a district Court has an opportunity to examine the record and observe the testimony and demeanor of witnesses, and evaluate their credibility, such decision will not be reversed unless clearly erroneous. In this instance, Judge Holderman is eminently correct. He patiently listened to and admitted Squibb's testimony concerning its alleged subjective good faith -- he simply did not believe it.

C. SQUIBB IMPROPERLY ATTEMPTS TO ARGUE MATTERS IMMATERIAL TO THE INSTANT APPEAL, INCLUDING THE ALLEGED MERITS OF ITS INVENTION, ITS INFRINGEMENT CASE, ETC.

It is now unquestioned in patent law that inequitable conduct in procuring any asserted claim of a patent renders the entire patent unenforceable. J.P. Stevens v. Lex Tex, supra. Therefore, theoretical questions, such as whether the patentee could have established infringement relying on inequitably procured claims are immaterial. Likewise, by engaging in inequitable conduct, the patentee forfeits any rights he may have in an alleged invention, whether or not it is commercially successful. Rewarding deception offends public policy.

Squibb's argues that its conduct is not objectionable because (a) it might have prevailed on what it alleges are broader claims; (b) its product was commercially successful or attractive; and (c) Hollister should not be able to assert defenses formulated after Hollister's product was designed. Squibb's argument simply ignores fundamental principles of patent law as well as the legal

requirement to comport oneself honestly before judicial, quasi-judicial, and administrative agencies. Perforce, patent lawyers bound by Rule 1.56(a) and engaged in ex parte prosecution must abide by this standard. See Hazel-Atlas Glass Co. v. Hartford Empire Co., 322 US 238, 88, L.Ed 1250, 64 S.Ct. 997, 61 USPQ 241 (1944)

Squibb's arguments undoubtedly are intended to suggest that Hollister lacked meritorious defenses to Squibb's charges. There is absolutely no basis for any such suggestion. Judge Holderman heard substantial evidence with regard to Hollister's defenses of invalidity and non-infringement. For example, Hollister evidence showed:

(1) many of the '363 patent claims were unquestionably invalid in view of Hamilton U.S. Patent No. 3,090,526 (JA 3971-76), showing a plastic channel and ring-type closure arrangement used in removably securing a plastic bag to another element in fluid-tight removable relation;

(2) Squibb at least constructively knew of, but did not disclose to the PTO, Hollister's commercial loop ostomy two-piece product, which would have invalidated numerous claims of the '363 patent under 35 USC §§102 and 103;

(3) claims 27-29 were admittedly not infringed;

(4) Squibb submitted Figure 11, a drawing which for the first time showed the claimed combination in a Rule 312 Amendment, long after the claims had been allowed; and

(5) Squibb "buried" pertinent references in a Rule 312 Amendment filed more than two years after it had become aware of these references through prosecuting counterpart foreign applications.

Although Judge Holderman heard extensive evidence on infringement, validity and so-called secondary considerations, he properly found it unnecessary to the decision here appealed from (JA 17). These aspects of this case are not at issue in this appeal.

D. SQUIBB'S ARGUMENTS IN SUPPORT OF  
ITS POSITION IN THIS APPEAL ARE  
TOTALLY UNSUPPORTED AND ERRONEOUS

In its brief of fifty pages Squibb makes numerous arguments, many of which are erroneous or based on erroneous assumptions. Hollister will here respond only to Squibb's most glaringly inaccurate arguments.

1. Unamended Claim 50 Was Properly  
Rejected Under 35 USC §112

Perhaps the most outrageous statement made in Squibb's brief is found on page 22, footnote 9, wherein Squibb states:

The trial court erroneously concluded that the rejection of unamended claim 50 in the parent application under 35 USC §112 was proper.

Squibb repeats its apparent belief that it may simply bypass examination in the PTO by arrogating to itself the prerogative of judging patentability. As previously pointed out herein, Squibb is now estopped from disputing the propriety of the Examiner's 35 USC §112 rejection (see pp. 16, supra.).

Moreover, Sears testified that the Examiner properly rejected original claim 50 under 35 USC §112 (JA 5235). Judge Holderman so found (JA 16). In making this finding, Judge Holderman made a factual determination. Judge Holderman agreed with the Examiner's position set out in the written record, Webster's dictionary, and Hollister's witnesses, and rejected the opinion of Arnold, Squibb's expert witness.

Arnold testified that the §112 rejection was not proper and that the unamended claim 50 complied with §112. Davis was permitted to testify at trial that unamended claim 50 did comply with 35 USC §112. However, Judge Holderman did not believe these after-the-fact attempted justifications by Davis and Arnold. Their testimony was flatly contradicted by Davis' previous admissions in the prosecution history of the parent application, and was simply incapable of belief.

In his rejection of unamended claim 50, the Examiner objected to the claim language that:

said pad or dressing aperture encircled by a coupling member  
... said bag aperture encircled by a second coupling member  
...

In his rejection, the Examiner stated:

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. (JA 3517).

Stated otherwise, the Examiner concluded that if one element "encircled" another element, those two elements must be coplanar, i.e., they must share at least one common plane. Squibb's drawings show that the coupling member does not share a common plane with the dressing aperture and is thus not coplanar with the aperture. Use of the word "encircled" was therefore incorrect and properly objectionable.

Squibb argues that "planar structures" are in dispute. There is no truth to their assertion. Sears agreed that the definition of "encircled" in Webster's Dictionary was not restricted to planar structures. The Examiner never stated that the definition of "encircling" was restricted to planar structures. Rather, as pointed out above, the Examiner's point was that the object being encircled must share a common plane with the object to be encircled.

Moreover, and most importantly for this case, Squibb acknowledged that this definition was correct and acquiesced in it when Davis amended claim 50 to overcome the rejection. Thus, the meaning of the word "encircled" ceased to be an issue on November 26, 1980 (JA 3520-28).

2. Judge Holderman Did Not Find  
That The Error Was "Ministerial"

Contrary to Squibb's statements, Judge Holderman did not find that Squibb's conduct constituted a "ministerial error". Rather, he said that the "error" could have been caught by a "ministerial person such as a paralegal" by comparing the different claim language (JA 13). Here, Judge Holderman was stating that this "error" was so easy to detect that any responsible patent attorney should have detected it under the circumstances. Judge Holderman also determined that this "error" was highly material in that it was the amendatory language of claim 50 which secured its allowance (JA 13).

In section II(a) of its brief, pages 40-43, Squibb sets forth a random collection of arguments unrelated to the titled topic. Hollister answers these arguments in turn.

Incredibly, Squibb argues that since its deception is of a type unreported in the case law, there can be no deceptive intent. In all probability, no other patentee would have attempted litigation under these circumstances. Squibb actually seeks to capitalize on the clever form of deception it practiced on the PTO and then absolve itself by stating there is no precedent for holding this conduct inequitable. Such argument appears to Hollister to be absurd.

Squibb further argues that:

This court has been careful not to allow materiality alone to become the touchstone of inequitable conduct.

That argument is not applicable where, as here, the patentee made a highly material misrepresentation to the PTO. Squibb's representation was material at least insofar as Squibb knowingly represented that a claim had been previously allowed when in fact it had been previously rejected. Davis knew the difference between these claims because he was the attorney who amended the rejected claim in order to achieve allowance. Further, Squibb knew the difference well before going to trial.

How could the difference between a rejected and an allowed claim not be a material difference? Judge Holderman correctly found materiality. However, Judge Holderman based his conclusion of inequitable conduct on findings of both materiality and intent, namely that Davis was grossly negligent -- at the very least -- by failing to catch the "error," especially in view of the many opportunities he had to do so. These findings of materiality and intent are fully supported by the evidence.

### 3. Squibb's Citation Of Legal Authority Is Largely Transparent

Squibb has throughout these proceedings cited various case authorities for certain propositions. While these propositions are generally true, they have no real application to the issues here. For example, at page 30 of its brief, Squibb states:

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 non-disclosure of the true facts was important in allowing the patent to issue.



Hollister does not quarrel with that statement of the law, only the application of the law to the facts of the instant case. Here it is clearly shown, both in the prosecution history and in the testimony of the witnesses that Squibb falsely represented rejected claim as an allowed claim. The importance of that misrepresentation is self-evident.

4. Squibb's Statements That Claims 1-8 Were Broader Than The Claims In The Application Is Not Supported By The Record, Nor Is It Material To This Action Under The Lex Tex Case

On page 11 of its brief, Squibb attempts to draw Hollister into a diversionary argument, stating that claims newly presented in the Preliminary Amendment (Patent Claims 1-8) were broader than the other claims in the application. Hollister of course disagrees, because these claims are narrower in several respects. Sears so testified (JA 5228).

Nevertheless, it is clearly the law that if any asserted claim is unenforceable for inequitable conduct, the entire patent is unenforceable. Lex Tex, supra. Hollister need not, and will not, elaborate on this fundamental precept nor need Hollister further discuss Squibb's arguments concerning the alleged scope of these claims.

5. Claim 6 Was Not Identical To Claim 50; Also Claim 6 Was Rejected As Being Indefinite

On page 9 of its brief, Squibb boldly argues that the language of unamended claim 50:

had been held acceptable twice previously in the first and second Official Actions

Similarly, on page 23 of its brief Squibb argues that the Examiner "had previously found no §112 defect in the identical language" of unamended claim 50. Squibb's statements are false. Squibb bases its argument on its contention that claim 6 is identical to amended claim 50 and that in the first two official actions the Examiner indicated that Claim 6, inter alia, would be allowable if rewritten in independent form.

Squibb's arguments on the Claim 6 issue are erroneous. Squibb voluntarily cancelled dependent claim 6, and replaced it with claim 50.

However, claim 50 was not identical to claim 6. That pertinent language in dependent claim 6 (from independent claims 1 and 41) is as follows:

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 ..."

The pertinent language of new claim 50 is as follows:

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 ... (JA 987).  
[Emphasis supplied].

Squibb's argument that unamended claim 50 was identical to dependent claim 6 ignores the express language of the claims.

Even assuming if claim 6 had been identical to claim 50, Squibb's argument that there were no §112 defects in the identical language of claim 6 would still be erroneous. When claim 50 was submitted as a replacement for claim 6, claim 41, upon which claim 6 depended, then stood rejected under 35 USC §112 as being indefinite, specifically in relation to the definition of what was "encircled" (JA 3500).

6. Judge Holderman's Finding That The Examiner Did Not Examine The Claims In The Continuation Application Is Not Clearly Erroneous

Judge Holderman found, based on the evidence, that the Examiner did not reexamine the language of claim 43 in the continuation application. In that regard, Judge Holderman stated,

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 on the evidence of the Examiner's action, as set forth in the Letter of Allowance which was mailed on June 23, 1983, did not take place. (JA 11) [Emphasis supplied]

Further, Judge Holderman stated:

Based upon the evidence, there is no indication that the Examiner went back and compared the language that had been represented to him as having been allowed, with the language that had been presented to him in the continuation application. (JA 11-12)

The evidence of record shows that the reason for allowing claims 50 and 51 appears in only one place, the letter of allowance dated June 23, 1983 (JA 3298). Judge Holderman based his findings on this Letter of Allowance. There the Examiner stated:

The claims are allowed in view of: ... Applicant's communication filed 02 July 1983 [sic-1982]. (JA 3298).

Certainly, there is no evidence in the record that the Examiner again examined these claims for §112 indefiniteness nor was there any reason for the Examiner to do so in view of Squibb's prior factual representation that this had already been done.

Squibb also cites the testimony of Michell in an attempt to support its argument that the Examiner reexamined the claims. At page 34 of its brief, Squibb states:

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 of the claims. (AP 5310-11).

While Michell did state that the Examiner must look at references and compare them with claims, he made this statement with respect to the prosecution of another patent --U.S. Patent No. 4,322,164 (JA 2532-2753). During cross-examination, Squibb's attorney presented Michell with the prosecution history of that other patent which was issued on a continuation application. Michell had been the primary examiner in connection with the parent and continuation applications. In that case, an Amendment After Final was presented in the parent case, but was not entered. The applicant therein then filed a continuation application and

represented to the Examiner that the continuation contained claims taken from the Amendment After Final in the parent case and otherwise. Naturally, because the Amendment After Final had not been entered in the parent case, a review of the new claims was in order. Also, in that case, the applicant stated that "it is believed that all of the claims ... are allowable" (JA 2701). Clearly, that statement is one of opinion, not fact.

The prosecution history of the '363 patent was considerably different. In the '363 patent, the Amendment After Final in the parent application was entered and Squibb represented that the rejected claims were indicated by the Examiner as being allowed. Therefore, because Squibb advised the Examiner that he had already considered and allowed these claims, no further review was needed. Squibb's attempt to use the prosecution history of another patent to support its argument that the Examiner reexamined claims 50 and 51 in the face of Squibb's factual representation that those claims were previously allowed is deplorable and must be summarily rejected.

Squibb can point to no evidence whatever to support its argument that the Examiner independently re-examined all of the claims in detail in the continuation application at least twice. Judge Holderman's finding, far from being clearly erroneous, is clearly supported by the record in this case.

7. Judge Holderman Did Not Find That The Examiner Must Rely Upon Representations Of An Applicant In A Continuation Application

Judge Holderman did not find that the Examiner must rely on the representations of the applicant. Squibb's statements to that effect are wrong. Rather, Judge Holderman found as follows:

I believe, because of the duty of candor that is imposed by law on the applicant, [an Examiner] has every right to rely upon the representations such as made on defendant's exhibit 2-43 and 2-44. (JA 12).

In short, Judge Holderman held that an Examiner has the right to rely on representations of the type made by Squibb in the preliminary amendment. In this action, the evidence clearly indicated that the Examiner did rely on those representations in allowing the claims 50 and 51, and their dependent claims (JA 5222, 5291).

In attempting to support its position, Squibb argues:

... 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. (Squibb's Brief, p. 44)

This argument is facetious as well as illogical. A representation that claims are allowable over the references is an undisguised statement of opinion by the applicant that he believes the claims are allowable over the references. That is not a statement of fact. Squibb's conduct here notwithstanding, only an examiner can allow a claim. In the instant case, Squibb made a statement of

fact, namely, that claims 43 through 63 in the continuation application had been previously allowed by the Examiner. It was a representation of fact that the examiner was entitled to rely on and, in this case, based on the evidence, Judge Holderman found that the Examiner did rely on it (JA 12). Michell testified that examiners can and traditionally have relied on such representations of fact in examining patent applications, and that applicants and their attorneys have a uncompromising duty to represent facts accurately to examiners (JA 5291-92). Squibb cannot effectively contradict this truth.

Next, at page 44-45 of its brief, Squibb argues that its actions are analogous to misstatements as to the meaning of a reference. Statements by an applicant about references in the record are clearly opinions, and in those cases, the examiner has the facts (the references) before him. The examiner is then positioned to weigh such statements of opinion. In this case, the representations made by Squibb were factual representations, pure and simple. Squibb reported falsely on a past event, namely, allowance of certain claims in the parent application.

Squibb's continued arrogance is reflected in its attempts to blame the Examiner for Squibb's sins, based on the argument that Squibb's "unartful statements invited examination" by the Examiner (Squibb brief, p. 45). These and other arguments by Squibb simply ignore the existence of the uncompromising duty of candor covered by 37 CFR 1.56 to applicants and their attorneys. Candor and

guile are two different things. Clearly, Squibb was totally derelict in its Duty of Candor.

Squibb even states that it is "not trying to benefit" from its failure to catch its "error", (Squibb Brief, p. 46) and seeks to absolve itself by stating that Hollister took several years to discover the "mistake". This position is as high-handed as its earlier position that Squibb, not the PTO, is the arbiter of patentability.

Here, Squibb is in effect "patting itself on the back" for having cleverly disguised its inequitable conduct, and then relying on the effectiveness of such disguise to argue that the "mistake" was insignificant.

If Squibb were truly not trying to benefit from its "error", (assuming it was an "error") Squibb had several choices: It could have gone back to the PTO, confessed forthrightly, and sought a reissue application. Or, it could have disclaimed all claims affected by error prior to taking action, or immediately upon "discovery". Of course, in order to qualify for reissue or disclaimer, the patentee must state that the error occurred "without deceptive intent". 35 USC §§251, 253. Squibb's failure to seek reissue or disclaimer further supports the inescapable inference that such error did not occur "without deceptive intent".



Theoretically, pursuant to 35 USC §288, had Squibb dedicated its tainted claims 9-26, it would have had the right to proceed for infringement of its remaining claims. Section 288, however, requires that the invalid claims have been obtained without deceptive intent. Squibb's failure to proceed in this way is tantamount to an admission of deceptive intent.

8. **Squibb's Argument That The Public Was Not Harmed Overlooks The Nature Of Public Injury And Ignores The Fact That Hollister Is A Member Of The Public**

In this case, Squibb violated its Duty of Candor by making material false representations. Those representations were justifiably relied upon by the Examiner in allowing the claims; and the result is severe harm to Hollister. Hollister is a member of the public. It is arrogant in the extreme to imply that subversion of a government agency charged with administration of patent law does not harm the public. One need not be a philosopher, a judge or an attorney to realize that the public is harmed whenever attempts are made to subvert public institutions, including the agencies and courts of the United States.

E. **35 USC §112 IS A PART OF THE PATENT LAW**

Throughout its brief, just as at trial, Squibb attempts to demean the statutory requirements set forth in 35 USC §112. Squibb seems to argue that failure of a claim to comply with §112 is not really a defect at all and hence a rejection on this ground should simply be overlooked, even where the need to overcome the


§112 rejection was at the heart of the inequitable conduct. The requirement that a claim be accurate as well as definite under 35 USC §112 has been reaffirmed in a number of cases including the a case of colossal importance in the steel industry, Kaiser Industries Corporation v. McLouth Steel 400 F.2d 36 (6th Cir. 1968) See also Standard Oil Company v. American Cyanamid Company, 774 F.2d 448 (Fed. Cir. 1985); Antonious v. Progroup, Inc., 699 F.2d 337 (6th Cir. 1983); Norton Company v. Bendix Corporation, 449 F.2d 553 (2nd Cir. 1971).

Consequently, it is futile for Squibb to contend that the failings of claims 50 and 51 as originally presented under 35 USC §112 were not serious and did not bear on validity.

#### VI. CONCLUSION

For all of the foregoing reasons, Hollister respectfully requests this Honorable Court to affirm the judgment entered by Judge Holderman on February 12, 1988 and find that Squibb's instant appeal was frivolous.

Respectfully submitted,

  
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