

2009-1196, -1197

---

---

United States Court of Appeals  
*for the*  
Federal Circuit

---

**FILED**  
U.S. COURT OF APPEALS FOR  
THE FEDERAL CIRCUIT

AUG 31 2009

U.S. COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT

TILLOTSON CORPORATION,

*Appellant,*

v.

INTERNATIONAL TRADE COMMISSION,

*Appellee,*

*and*

CARDINAL HEALTH, INC., CARDINAL HEALTH 200, INC., and  
CARDINAL HEALTH MALAYSIA 211 SDN. BHD.,

*Intervenors.*

*and*

SMART GLOVE HOLDINGS, SDN. BHD, SMART GLOVE CORPORATION SDN. BHD.,  
HENRY SCHEIN, INC., and HSI GLOVES, INC.,

*Intervenors.*

---

---

*On Appeal from the United States International Trade Commission in  
Investigation Nos. 337-TA-608 and 612*

---

---

**REPLY BRIEF FOR APPELLANT**

WILLIAM D. BELANGER  
PEPPER HAMILTON, LLP  
*Attorneys for Appellant*  
125 High Street  
15<sup>th</sup> Floor, Oliver Street Tower  
Boston, MA 02111  
(617) 204-5103

CHARLES H. CARPENTER  
GREGORY C. DORRIS  
*Attorneys for Appellant*  
PEPPER HAMILTON, LLP  
600 14<sup>th</sup> Street, N.W.  
Washington, DC 20005  
(202) 220-1200

AUGUST 31, 2009

**CERTIFICATE OF INTEREST**

Counsel for the appellant Tillotson Corporation (“Tillotson”) certifies the following:

1. The full name of every party or amicus represented by me is:

Tillotson Corporation

2. There are no real parties in interest represented by me that are not named appellants.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Tillotson Corporation does not have a parent corporation and no publicly held company owns 10% or more of its stock.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or are expected to appear in this court are:

<b>PEPPER HAMILTON, LLP</b> William D. Belanger Gregory C. Dorris Charles H. Carpenter Alison L. McCarthy Aaron J. Levangie R. Brad McMahon Daniel J. Boland Nicole D. Galli Michael T. Renaud Matthew D. Foster Heather Kilgore Weiner	<b>CHOATE HALL &amp; STEWART LLP</b> Daniel C. Winston Mark G. Edgerton Matthew S. Barrett
<b>KING &amp; SPALDING LLP</b> Anthony B. Askew Katrina M. Quicker	

Ethan Horwitz Gilbert B. Kaplan Jeffrey M. Telep Thomas C. Lundin Jr. Jason M. Pass Matthew S. Dunne Amy J. Stanley Eric Sophir Brent R. Bellows Johnathan D. Ball Charles A. Pannell Gina Glantz Holmes J. Hawkins John L. Harmonson John Baldwin Richard C. Pettus Jennifer Lutz Dawn Hart Suzanne S. Williams Ronen Arad Robert E. Richards Gary J. Greco Kevin M. Dinan John P. Sheesley Thomas C. Lundin Jr. Jason M. Pass Matthew S. Dunne Amy J. Stanley	
--	--

## TABLE OF CONTENTS

	<b>Page</b>
CERTIFICATE OF INTEREST .....	i
TABLE OF AUTHORITIES .....	v
INTRODUCTION .....	1
ARGUMENT .....	4
A. The Amendment of “initially exerting a predetermined pressure” to “initially exerting an initial pressure” Did Not Effect a Substantive Change in Claim Scope.....	4
1. The Commission’s Explanation of Its Claim Construction is Internally Inconsistent and Supports Reversal. ....	4
2. The Claim As a Whole Was Not Broadened, Even Using the Commission’s Claim Construction.....	6
3. The Reissue Prosecution Further Supports Reversal.....	9
B. The Intervenor’s Best Mode Defense is Not Properly a Subject For This Appeal. ....	11
1. If the Court Considers Intervenor’s Best Mode Defense, The ALJ’s Rejection of That Defense Should Be Affirmed.....	12
(a) The Best Mode Analysis Requires That An Inventor Possess A Best Mode, And If So, That The Written Description Teaches One Of Ordinary Skill In The Art How To Practice The Best Mode. ....	13
(b) Applying Federal Circuit Precedent, The ALJ Correctly Concluded That There Was No Best Mode Violation. ....	17
(c) The ALJ Properly Concluded That The Reichhold 68073 Latex Did Not Constitute A Best Mode For Practicing The Invention.....	18

2. The ALJ Properly Concluded That Intervenors Failed To  
Establish That The Written Description Does Not Disclose  
The Best Mode.....26

DECLARATION OF AUTHORITY PURSUANT TO .....30

CERTIFICATE OF SERVICE .....31

CERTIFICATE OF COMPLIANCE.....32

## TABLE OF AUTHORITIES

	<b>Page(s)</b>
<b>Cases</b>	
<i>ACTV, Inc. v. Walt Disney Co.</i> , 346 F.3d 1082 (Fed. Cir. 2003) .....	1
<i>AllVoice Computing PLC v. Nuance Comm'ns, Inc.</i> , 504 F.3d 1236 (Fed. Cir. 2007) .....	13
<i>BayerAG v. Schein Pharm., Inc.</i> , 301 F.3d 1306 (Fed. Cir. 2002) .....	24, 26
<i>Beloit Corp. v. Valmet Oy</i> , 742 F.2d 1421 (Fed. Cir. 1984) <i>cert. denied</i> , 472 U.S. 1009 (1985) .....	11, 12
<i>Brooktree Corp. v. Advanced Micro Devices, Inc.</i> , 977 F.2d 1555 (Fed. Cir. 1992) .....	14
<i>Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.</i> , 381 F.3d 1371 (Fed. Cir. 2004) .....	13
<i>College Net, Inc. v. Apply Yourself, Inc.</i> , 418 F.3d 1225 (Fed. Cir. 2005) .....	13
<i>Eli Lilly and Co. v. Barr Labs, Inc.</i> , 251 F.3d 955 (Fed. Cir. 2001) .....	<i>passim</i>
<i>High Concrete Structures, Inc. v. New Enter. Stone And Lime Co.</i> , 377 F.3d 1379 (Fed. Cir. 2004) .....	14
<i>Hockerson-Halberstadt, Inc. v. Converse Inc.</i> , 183 F.3d 1369 (Fed. Cir. 1999) .....	1, 7, 8, 9
<i>Hybritech, Inc. v. MonoclonalAntibodies, Inc.</i> , 802 F.2d 1367 (Fed. Cir. 1986) .....	13

<i>Kyocera Wireless Corp. v. International Trade Commission</i> , 545 F.3d 1340 (Fed. Cir. 2008) .....	1
<i>Liquid Dynamics Corp. v. Vaughan Co., Inc.</i> , 449 F.3d 1209 (Fed. Cir. 2006) .....	27
<i>Osram GmbH v. Int'l Trade Comm'n</i> , 505 F.3d 1351 (Fed. Cir. 2007) .....	13
<i>Randomex, Inc. v. Scopus Corp.</i> , 849 F.2d 585 (Fed. Cir. 1988) .....	13
<i>Spectra-Physics Inc. v. Coherent, Inc.</i> , 827 F.2d 1524 (Fed. Cir. 1987) .....	27
<i>Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.</i> , No. 2007-1448, 2008 WL 3891543 (Fed. Cir. Aug. 25, 2008) .....	23
<i>TALtech Ltd. v. Esquel Apparel, Inc.</i> , No. 2007-1506, 2008 WL 2165996 (Fed. Cir. 2008) .....	24, 25
<i>U.S. Gypsum Co. v. Nat'l Gypsum Co.</i> , 74 F.3d 1209 (Fed. Cir. 1996) .....	13, 24, 25
<i>Wahl Instr., Inc. v. Acvious, Inc.</i> , 950 F.2d 1575 (Fed. Cir. 1991) .....	15
<i>Young Dental Mfg. Co., Inc. v. Q3 Special Products, Inc.</i> , 112 F.3d 1137 (Fed. Cir. 1997) .....	<i>passim</i>

## INTRODUCTION

The principal issue on appeal is whether changing the word “predetermined” to “initial” impermissibly broadened the claim on reissue. Both the Commission and the Intervenor seek to reduce this appeal to a simplistic semantic comparison of these two words. In so doing, however, they fail to consider how these words are actually used in the context of the claim as a whole, as required by this Court’s precedent. “[T]his court does not interpret claim terms in a vacuum, devoid of the context of the claim as a whole.” *Kyocera Wireless Corp. v. International Trade Commission*, 545 F.3d 1340, 1347 (Fed. Cir. 2008), citing *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1374 (Fed. Cir. 1999) (“proper claim construction . . . demands interpretation of the entire claim in context, not a single element in isolation.”); *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003) (“While certain terms may be at the center of the claim construction debate, the context of the surrounding words of the claim also must be considered . . .”).

Tillotson should not be deprived of its valuable and hard earned patent rights based on a simple comparison of semantics.

When the claim is considered as a whole, rather than as one isolated word, it is clear that the claim was not broadened because no hypothetical product could infringe the reissued claim but not also infringe the original claim. Indeed, the

Commission's efforts to explain its construction of "predetermined" prove too much.

The Commission explains that its construction merely requires "a determination, by any means, of what pressure the glove exerts on a hand when the glove is first donned." Comm'n Br. at 27. While the Commission speculates that an "initial pressure" could be "an undetermined, or random, amount of initial pressure..." this is simply not true in the context of the entire claim. Comm'n Br. at 31. To the contrary, the claim element at issue describes an elastic property of the glove material called "relaxation." It thus expressly requires that the initial pressure must be determined so that it can be compared to a reduced pressure to calculate the relaxation property of the material. The Commission nowhere explains, because it cannot, how one would evaluate the difference between a first pressure (initial or predetermined) and a reduced pressure without determining that first pressure by some means and then comparing it to a reduced pressure. Once this "initial pressure" is measured – and it must be to determine whether the relaxation element of the claim is satisfied – that "initial pressure" becomes a "predetermined pressure" under the Commission's construction. Rather than proving invalidity, the Commission's arguments establish that this change in language did not impermissibly broaden the claim.

Similarly, the Commission's only basis for concluding that the reissue declaration was defective is its conclusion that the term "initial" was broader than the word "predetermined." This conclusion, however, turns the claim construction exercise on its head. The reissue declaration, which is part of the intrinsic record, is consistent with and supports the conclusion that the claim was not broadened. Therefore, applicants did not need to explain why the claim was changed because they did not change its scope. The reissue declaration was entirely sufficient to explain this non-substantive change in claim language, which did not affect claim scope.

In addition, Intervenor's also assert invalidity based on a best mode argument, despite that this defense was not ruled upon by the Commission and is therefore not appealable. Even if this defense is considered on its merits, it should be rejected as the ALJ properly rejected Intervenor's best mode defense. First, the ALJ evaluated the credibility of the inventor, Mr. DeBecker, at trial and concluded that he did not subjectively consider a particular latex, Reichhold 68073, to be the best latex for his invention. [A-115-A117]. Second, the ALJ found as fact that, even if Mr. DeBecker held such a subjective belief, it would not result in a failure to disclose the best mode, because, in the context of the invention, the selection of Reichhold 68073 was a production detail that did not need to be disclosed. [A116-A117] Thus, Intervenor's best mode defense is not supported by clear and

convincing evidence and does not provide alternate grounds for affirmance of the Commission's finding of no violation. This Court should reverse and remand with direction to enter relief in favor of Tillotson.

### **ARGUMENT**

**A. The Amendment of “initially exerting a predetermined pressure” to “initially exerting an initial pressure” Did Not Effect a Substantive Change in Claim Scope.**

Tillotson is not proposing that the word “predetermined” is synonymous with the word “initial,” nor is Tillotson suggesting that the word “predetermined” has no meaning. Comm'n Br. at 15. This appeal does not turn on a mere consideration of semantics. Rather, Tillotson is proposing that these terms should be read in the context of the entire claim, the patent and its prosecution history. When all of this material is considered, it is clear that this amendment to the claim language did not expand the scope of the claim.

**1. The Commission's Explanation of Its Claim Construction is Internally Inconsistent and Supports Reversal.**

The Commission construction of “predetermined pressure” requires a pressure that is “known in advance of putting the glove on.” [A10-A11] The Commission acknowledges that this predetermined pressure (as well as the claimed initial pressure) is determined “by simulating the predetermined pressure with the 100% Modulus Test.” *Id.* As the Commission admits in its Brief, “the

Commission's construction merely requires a determination, by any means, of what pressure the glove exerts on a hand when the glove is first donned." Comm'n Br. at 27. This construction, however, would also apply to an "initial pressure," which is measured using the exact same 100% Modulus Test so that it can be compared to a second, reduced pressure to evaluate the relaxation property of the claimed glove. There is a difference of semantics, but not one of substance, between the original and reissued claim.

The Commission strenuously argues that it has not imported a mental step into the claim. Comm'n Br. at 23-28. The Commission, however, does not apply this construction consistently when evaluating whether the claim was broadened on reissue. Indeed, absent a mental step or "cognitive function," the Commission is left to argue that the claims were broadened simply because "initial" does not mean "predetermined."

When attempting to justify why the original claim was narrower than the reissued claim, the Commission argues that "the pressure the glove will exert on a hand is determined during the design and/or manufacture of the glove, i.e., before the glove is worn." Comm'n Br. at 26. This argument, however, directly conflicts with the Commission and ALJ's findings that "[t]here is no requirement that [the] 'predetermined pressure' be a specific starting pressure or that the designer of the glove 'knowingly select a specific pressure.'" [A11]. Indeed, when attempting to

explain why it did not import a mental step into the claim the Commission argues that its construction “does not require a specific selection or determination of a specific pressure in advance...” Comm’n Br. at 23.

If no mental step is required, then the “predetermined pressure” can be any measured value. The “initial pressure,” likewise, can be any measured value. Thus, the only apparent difference between the Commission’s interpretation of “predetermined pressure” and the Commission’s interpretation of “initial pressure” is the improper requirement of a cognitive function. The Commission expressly admits, however, that “the claims of the ‘616 Patent are not directed to a mental process; rather, they are directed to a product, i.e., a glove.” Comm’n Br. at 24. The Commission cannot have it both ways. Either the Commission’s construction improperly imports a mental step into a product claim, or the Commission improperly held that the claims were broadened on reissue. In either case the Commission’s finding should be reversed.

**2. The Claim As a Whole Was Not Broadened, Even Using the Commission’s Claim Construction.**

The Commission incorrectly claims that “Tillotson does not dispute the Commission’s finding that, under the Commission’s construction, the asserted claims are invalid.” Comm’n Br. at 15. To the contrary, even using the Commission’s construction, there is no evidence that the claim is impermissibly

broadened because there is no evidence that any hypothetical glove would infringe the reissue claim without also infringing the original claim.

The claim as a whole, before and after reissue, is directed to a glove with material that exhibits certain elastic properties, including pressure relaxation. The Commission posits that “a glove that exerts an arbitrary amount of ‘initial pressure,’ without any advance determination ...but that relaxes to less than about 50% of the ‘initial pressure’ that it exerts on the hand, would meet the ‘initial pressure’ limitation of the reissue claims and therefore infringe the reissued claims.” Comm’n Br. at 31. The only conceivable way to determine whether a glove relaxes to less than about 50% of the “initial pressure,” however, is to measure the initial pressure and compare it to a reduced pressure. As soon as the initial pressure is measured, it is by definition known. This measurement is, in turn, “a determination, by any means, of what pressure the glove exerts on a hand... .” Comm’n Br. at 27. It therefore becomes a “predetermined pressure” under the Commission’s construction. Thus, the Commission’s hypothetical glove would infringe both the original and reissue claim.

This Court’s decision in *Hockerson-Halberstadt, Inc.* is particularly relevant here. In that case, the lower court granted summary judgment of invalidity, finding that the claims had been impermissibly broadened during reexamination. The original claim required a support band that inclined upwardly starting from the

lower rim of the heel portion of a shoe. The amended claim element did not limit itself to a support band that started from the lower rim. As this Court noted “that element, standing alone, would cover the configurations [not covered by the original claim].” *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1374 (Fed. Cir. 1999). The Court, however, went on to consider the entire claim, finding that an “additional limitation constrains the amended claim to cover, like the original claim, only the Fig. B configuration.” *Id.* This Court reversed, finding that the claim as a whole was not broadened. *Id.* (reversing summary judgment based on broadening during reexamination).

As with *Hockerson-Halberstadt*, the Commission erred because it did not evaluate the claim as a whole. The Commission tacitly acknowledges that fact when it contends that “Tillotson confuses the relaxation limitation with the ‘predetermined’ pressure limitation,” Comm’n Br. at 20. It is the Commission that is confused on this point. Every time the term “predetermined pressure” is used in the patent specification, it is used in the context of the elastic property of relaxation. [A736, A738 (3:53-65); A739 (4:7-18)]. Moreover, it is used to describe an elastic property of the claimed glove. Indeed, the patent directly and consistently links the term “predetermined pressure” to the concept of pressure relaxation. [A739 (3:50-4:18); A739 (6:18-20); A883.104]. These terms must therefore be considered together, as “[t]hese limitations do not exist independently,

but rather operate together to define the same aspect of the claim.” *Hockerson-Halberstadt*, 183 F.3d at 1375. When read as a whole, it is clear that the “initial pressure” must be measured. It therefore has the same meaning, in context, as a “predetermined pressure.” The claim as a whole was not broadened and the Commission’s finding should be reversed.

### **3. The Reissue Prosecution Further Supports Reversal.**

The Commission attempts to explain away the prosecution history by claiming that “nothing in the reissue prosecution states that the Miller Patent, or any other prior art, met the ‘predetermined pressure’ limitation.” Comm’n Br. at 21. Rather than attempting to analyze the intrinsic record, which directly refutes its conclusion, the Commission dismisses the statements on reissue as “irrelevant.” *Id.* at 22. Indeed, the Commission attempts to flip the claim construction analysis on its head. Rather than construing the claim terms in accordance with the ‘616 Patent and file history, the Commission uses a general dictionary to define the word “predetermined” and then critiques the file history because it does not support this dictionary based construction. This is not proper.

Tillotson clearly and unequivocally stated on reissue that original claim 1, which claimed relaxation from a predetermined pressure to a reduced pressure, was “too broad” because the prior art gloves would relax from an initial pressure to a reduced pressure. More specifically, applications stated the following:

I believe the Original Patent to be partly inoperative by reason of Patentee claiming more than Patentee had a right to claim in claim 1 of the Original Patent. Specifically, claim 1 of the Original Patent is *too broad* because the prior art includes elastomeric gloves, both nitrile rubber and natural rubber gloves, that have relaxation properties such that the prior art gloves would relax from an initial pressure to a reduced pressure substantially less than 80% of the initial pressure.

[A883.122](emphasis added). The “prior art” referenced in this statement includes the Miller patent. *Id.* This statement makes clear that original claim 1, claiming a glove with relaxation from a predetermined pressure to a reduced pressure, was in fact broader than the prior art, which exhibits relaxation from an initial pressure to a reduced pressure. This statement is not “irrelevant,” rather, it conclusively shows that Tillotson did not broaden the claims when changing the term “predetermined pressure” to “initial pressure” during reissue prosecution.

Nor does Tillotson claim that it “undertook the known risk of reissue prosecution in order to ... make no change to the claims whatsoever.” Comm’n Br. at 15. To the contrary, Tillotson properly undertook reissue to narrow the claims of the original patent in view of prior art it discovered after the original patent issues. This motivation is clearly presented in the reissue declaration, where Mr. Tillotson states:

Tillotson Corporation does not seek to enlarge the scope of the original patent which is the subject of this reissue application. Instead Tillotson Corporation seeks to narrow the claims of the original patent in view of prior art which has come to the attention of

Tillotson Corporation and its attorneys since the issuance of the original patent.

[A861].

Thus, Tillotson set out to narrow its claims, and indeed accomplished that goal as amply illustrated by the reissue prosecution and the multiple additional limitations contained within the reissued claims.

**B. The Intervenors' Best Mode Defense is Not Properly a Subject For This Appeal.**

Intervenors' best mode defense was properly rejected by the ALJ in his Initial Determination [A115-A117]. In affirming the ALJ's finding of no violation of Section 337, the Commission based its affirmance solely on grounds that the asserted claims of the '616 Patent were invalid as having been impermissibly broadened during reissue prosecution and because of a defective reissue declaration. The Commission simply adopted the ALJ's rejection of Intervenors' best mode defense.

Accordingly, for the reasons set forth clearly in *Beloit Corp. v. Valmet Oy*, 742 F.2d 1421 (Fed. Cir. 1984) cert. denied, 472 U.S. 1009 (1985), Intervenors' best mode defense is not properly reviewable at this time. As stated in *Beloit*,

. . . [T]his court does not sit to review what the commission has not decided. Nor will it review determinations of presiding officers on which the Commission has not elected to provide this court with its views.

*Beloit*, 742 F.2d at 1423.

Here Intervenor's are similarly attempting to "back-door" an appeal of their best mode defense. As in *Beloit*, this attempt should be rejected as premature. Because the Commission did not rely on Intervenor's best mode defense, that defense, in accordance with *Beloit*, should not be considered on this appeal.

**1. If the Court Considers Intervenor's Best Mode Defense, The ALJ's Rejection of That Defense Should Be Affirmed.**

The ALJ properly rejected the best mode defense, finding that Intervenor's did not establish by clear and convincing evidence that the inventors of the '616 Patent failed to disclose their best mode for practicing their invention. [A115-A117] The ALJ's decision was premised on two findings of fact, each of which would be sufficient by itself to defeat the defense. First, the ALJ found as fact that Intervenor's key contention – that one of the inventors, Mr. DeBecker, subjectively considered a particular latex, Reichhold 68073, the best latex for his invention – was not supported by clear and convincing evidence. [A115-A116]. Second, the ALJ found as fact that, even if Mr. DeBecker held such a subjective belief, it would not result in a failure to disclose the best mode, because, in the context of the invention, the selection of Reichhold 68073 was a production detail that did not need to be disclosed. [A116-A117].

These two findings of fact by the ALJ are entitled to deference on appeal and should only be overturned if the Court determines that, taking the record as a

whole, they are unsupported by substantial evidence – *i.e.*, such relevant evidence as a reasonable mind would accept as adequate to support a conclusion. *See Osram GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1355 (Fed. Cir. 2007); *College Net, Inc. v. Apply Yourself, Inc.*, 418 F.3d 1225, 1230 (Fed. Cir. 2005). As explained below, since more than substantial evidence supports the ALJ’s findings of fact, his rejection of Intervenor’s best mode defense should not be disturbed.

**(a) The Best Mode Analysis Requires That An Inventor Possess A Best Mode, And If So, That The Written Description Teaches One Of Ordinary Skill In The Art How To Practice The Best Mode.**

Like all challenges to the validity of a duly issued patent, a violation of the best mode requirement must be proved by clear and convincing evidence. *AllVoice Computing PLC v. Nuance Comm’ns, Inc.*, 504 F.3d 1236, 1240 (Fed. Cir. 2007) (citing *U.S. Gypsum Co. v. Nat’l Gypsum Co.*, 74 F.3d 1209, 1212 (Fed. Cir. 1996)). A best mode violation requires that the inventor knew of and concealed a better mode than what was disclosed for making and using the claimed invention. *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 381 F.3d 1371, 1378 (Fed. Cir. 2004) (quoting *Randomex, Inc. v. Scopus Corp.*, 849 F.2d 585, 588 (Fed. Cir. 1988) (“It is concealment of the best mode of practicing the claimed invention that section 112 para. 1 is designed to prohibit.”); *Hybritech, Inc. v. MonoclonalAntibodies, Inc.*, 802 F.2d 1367, 1384-85 (Fed. Cir. 1986) (“in order to find that the best mode requirement is not satisfied, it must be shown that the

applicant knew of and concealed a better mode than he disclosed”)). Thus, “invalidity for omission of a better mode than was revealed requires knowledge of and concealment of that better mode.” *Id.* (citing, e.g., *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1575 (Fed. Cir. 1992) (“Invalidity for violation of the best mode requires intentional concealment of a better mode than was disclosed.”)).

Courts apply a two-prong analysis in determining whether a patent complies with the best mode requirement. *Eli Lilly and Co. v. Barr Labs, Inc.*, 251 F.3d 955, 963 (Fed. Cir. 2001). First, the fact finder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention. *Id.* This first prong involves a subjective inquiry, focusing on the inventor’s state of mind at the time of filing. *Id.*; see also *High Concrete Structures, Inc. v. New Enter. Stone And Lime Co.*, 377 F.3d 1379, 1383 (Fed. Cir. 2004) (requiring “deliberate concealment” because the best mode requirement “is not violated by unintentional omission of information that would be readily known to persons in the field of the invention”).

Only if the answer to the first inquiry is affirmative does the court reach the second prong, in which the fact finder must determine whether the written description disclosed the best mode such that one of ordinary skill in the art could practice it. *Eli Lilly*, 251 F.3d at 963. “This inquiry is largely an objective inquiry

that depends upon the scope of the claimed invention and the level of skill in the art.” *Young Dental Mfg. Co., Inc. v. Q3 Special Products, Inc.*, 112 F.3d 1137, 1144 (Fed. Cir. 1997).

Importantly, the Federal Circuit has made clear that the best mode requirement does not extend to production details or routine details. *Eli Lilly*, 251 F.3d at 963 (citing *Young Dental*, 112 F.3d at 1143). Production details relate to “commercial and manufacturing considerations such as equipment on hand, certain available materials, . . . relationships with suppliers,” and other details. *Id.* (citing *Wahl Instr., Inc. v. Acvious, Inc.*, 950 F.2d 1575, 1581 (Fed. Cir. 1991). “Routine details, on the other hand, implicate the quality and nature of invention, but their disclosure is unnecessary because they are readily apparent to one of ordinary skill in the art.” *Id.*

In *Eli Lilly & Co. v. Barr Labs*, the patents in suit claimed the compound fluoxetine hydrochloride (the active ingredient in Prozac) and identified p-trifluoromethylphenol as a “starting material” for making the claimed compound. *Eli Lilly*, 251 F.3d at 961. The inventors at first purchased commercially available quantities of the starting material, then later developed their own method of synthesizing the starting material that they testified was “superior.” *Id.* The inventors also experimented with various solvents for recrystallizing the claimed

compound and eventually found a “preferred” solvent that produced a higher yield and higher purity than other solvents. *Id.* at 962.

The court in *Eli Lilly* concluded that the patents satisfied the best mode requirement for two reasons. First, although the patents identified the starting material for the claimed compound, they did not “claim[] [the starting material] itself or a method for synthesizing it. Thus, while the best mode for developing [the claimed compound] involves use of [the starting material], the claimed inventions do not cover [the starting material] . . . .” *Id.* The court also rejected the best mode challenge because “the record insistently demonstrates that [the starting material] was commercially available” at the time the patentee filed its original application. *Id.* at 964-65. The court characterized the argument as “paradigmatic examples of production details that the law excepts from best mode disclosure.” *Id.* at 965; *see also id.* at 966 (concluding that choosing a solvent for performing recrystallization constituted a routine detail that fell outside the ambit of best mode disclosure).

Similarly, the Federal Circuit in *Young Dental* determined that there was no best mode violation where the inventor did not disclose the grade of plastic used for the body and gears of his preferred embodiment. *Young Dental*, 112 F.3d at 1145. The court stated that the patentee “actually disclosed that he preferred that the parts be made from Lexan and Celcon; he merely failed to disclose the

particular grades of these two plastics in his contemplated best mode.” *Id.* The court further found that “the evidence of record shows that, given the disclosure of the types of plastic, it would have been readily apparent to one of skill in the art to select the particular grade of plastic that would result in efficient [] operation.” *Id.* Further, there was no showing that a particular grade was necessary and concealed. *Id.*

**(b) Applying Federal Circuit Precedent, The ALJ Correctly Concluded That There Was No Best Mode Violation.**

In determining that the inventors satisfied the best mode requirement, the ALJ fully understood and properly applied the applicable legal standard regarding 35 U.S.C. § 112 ¶ 1. [A111-112]. Specifically, relying on *Eli Lilly* and other key Federal Circuit decisions, the ALJ understood that the best mode inquiry involves (1) determining “whether, at the time of filing the patent application, the inventor possessed a best mode of practicing the invention” and if so, then (2) determining if one reasonably skilled in the art could practice the best mode. [A112]. The ALJ also understood that the first inquiry is subjective whereas the second inquiry is objective. *Id.* Similarly, the ALJ quoted and relied on the Federal Circuit’s holding in *Eli Lilly* that “the best mode requirement does not extend to production details or routine details.” [A117](quoting *Eli Lilly*, 251 F.3d at 963).

Applying these legal principles, the ALJ correctly determined that the inventors did not consider using Reichhold 68073 to be the best mode *See id.* at 94-95. The ALJ also correctly determined that Intervenor failed to clearly and convincingly show that the written description does not disclose the best mode. *Id.* at 95-96.

**(c) The ALJ Properly Concluded That The Reichhold 68073 Latex Did Not Constitute A Best Mode For Practicing The Invention.**

The evidence establishes that the inventors did not subjectively believe that Reichhold 68073 nitrile latex was the best mode for producing a *relaxing* glove and that Tillotson's use of Reichhold 68073 was driven by commercial considerations relating to the overall production of gloves -- not the production of a relaxing glove. [A8882 (689:13-18, 691:7-11, 691:19-25); A8885 (702:16-703;4); A8922 (851:1 - 852:5, 851:20-25)]. Indeed, Mr. DeBecker testified that he did not believe that the particular latex made the N-DEX glove different from what came before. [A8881 (686:3-5)]. Mr. DeBecker also testified that, at the time of the invention, the inventors did not believe that they needed the specific Reichhold 68073 nitrile latex to make the claimed invention, i.e., a relaxing glove. [A8885 (702:16-22)]. Instead, he testified that the inventors "knew that we could get good relaxation with other latexes. I think it shows in my lab book we could get good relaxation with a [Reichhold] 68074 [nitrile latex] also. *So we realized that what*

*we needed was a carboxylated nitrile butadiene latex, not that we necessarily needed the specific 68073 latex.” Id. (emphasis added); see also [AA9794 at Q&A 352-356; A9797; A9798; A9800; A9802; A9805; A9808; A9811; A9793 at Q&A 348](evidence that Tillotson experimented with nitrile latexes after the issuance of both the Original Patent and the Reissue Patent). Thus, the evidence establishes that the inventors did not believe that Reichhold 68073 was “better” for making the claimed invention and therefore the best mode for practicing the invention.*

Intervenors ignore the evidence above and focus heavily on Mr. DeBecker’s deposition testimony to argue that the inventors “preferred” latex 68073. Int. Br. at 13-16, 51-52. But at trial, Mr. DeBecker explained his deposition testimony by testifying, in part, that “if you look at the next question, I said that, yes, you *could* make a glove that relaxes with [68074] also. It is just that there were other advantages.” [A8882 (691:1-11)] (emphasis added). And in response to questioning by the Staff, Mr. DeBecker testified that the “other advantages” that caused Tillotson to use Reichhold 68073 latex involved production details and commercial considerations. [A8882 (691:19-25), A8885 (702:23 - 703:4), A8922 (851:1-852:12)].

Specifically, Mr. DeBecker testified that at the time of developing the N-DEX glove Tillotson was already making nitrile fabric supported gloves using Reichhold 68073 nitrile latex, was buying tanks of Reichhold 68073 nitrile latex

regularly, and was having it stored in storage tanks at the manufacturing plant. [A8922 (851:20-25, 851:1-852:12)]. Tillotson would have needed to add another storage tank if a different nitrile latex was used for making the new unsupported glove. [A8922 (852:1-3, 851:1-852:12)]; *see also* [A6703-A6704 at 15-16](discussing production details). Mr. DeBecker testified that “it was really simpler to use that [nitrile latex] which Tillotson already had on hand.” [A8922 (851:1 - 852:5, 851:1 -852:12)]. Thus, the choice of nitrile latex was based “on commercial considerations that do not relate to the quality or nature of the invention.” *Young Dental*, 112 F.3d at 1144 (Fed. Cir. 1997).

The excerpts from Mr. DeBecker’s laboratory notebooks on which Intervenors rely also fail to show, much less clearly and convincingly prove, that the inventors “preferred” latex 68073 for the production of a relaxing glove. Int. Br. at 16-18. Instead, what these notebooks show is that, at the time of the invention, Mr. DeBecker experimented with different formulations for several different types of gloves, including laminated, supported, and powder-free gloves. When so doing, he varied several components, including the latex on occasion. [A8870-A8871 (642:5-646:12); A8872-A8881 (649:18-684:4); A8921 (845:13-846:19); A9760-A9795]; *see also* [A6702] (discussing the Mr. DeBecker’s laboratory notebooks). Intervenors acknowledge this fact in their petition, stating that the “primary goal of the experiments was to evaluate various latexes for use in

natural rubber/nitrile rubber laminate hand gloves and pure nitrile gloves.” Int. Br. at 16. Importantly, the fact that Mr. DeBecker used different latexes and obtained different results for different glove types does not establish either a “preference” for latex 68073 for the production of a relaxing glove or a belief that this latex was “better” as Intervenors argue. Indeed, Mr. DeBecker specifically testified that his success and failures would vary depending on the glove type, and that they would not be the same for pure nitrile gloves. [A8922 (849:20-23); A6702].<sup>1</sup>

Also, when describing another latex -- the Reichhold 68074 latex -- Mr. DeBecker did not testify that this latex would result in holes if used in an N-DEX glove as Intervenors suggest. *See* Int. Br. at 16. Instead, he testified that use of this latex in “unsupported gloves prior to the N-DEX” would develop holes. [A8922 (851:8-25)]. Intervenors thus have no basis for arguing that this latex is inferior.

Mr. DeBecker has also clarified that the recipe identifying “latex 68073” set forth on pages 17 and 18 of Intervenors’ Brief is not a “preferred” recipe. Specifically, when counsel for the Smart Glove Intervenors attempted to characterize this recipe as “special” at trial, Mr. DeBecker corrected him:

Q. Does this page include what you have termed the special recipe for example 1 of the [Reissue] patent?

---

<sup>1</sup> The reference to the 68073 latex concerns a production detail – stripping a glove from the manufacturing glove form. *See* Int. Br. at 16-17.

- A. You mean -- excuse me. Could you repeat, please?
- Q. Yes. You have described, haven't you, in the past, the special recipe for making the glove, according to the '616 patent, haven't you?
- A. I'm not sure what you mean, special recipe.
- Q. Well, is it a recipe for making --
- A. Yes, this is a recipe *for making the glove* that we were making on the pilot line.

[A8868 (636:3-15)](emphasis added). Thus, Mr. DeBecker made clear that the recipe identifying "latex 68073" is one recipe for making the claimed glove -- not a "special" or preferred recipe as Intervenors argue. *Id.*<sup>2</sup>

In view of the evidence described above, all of which was before the ALJ in these investigations, the ALJ determined that the inventors did not believe the Reichhold 68073 to be the "best" latex and that this latex thus did not constitute a "best mode" at the time of the invention. [A115-116]. In so doing, the ALJ relied in part on Mr. DeBecker's testimony that one could get "good relaxation with other latexes as well" and that inventors did not believe that the 68073 was the best latex for producing a relaxing glove. [A115] (quoting DeBecker, Tr. 702:16-17).

The ALJ also relied on Mr. DeBecker's testimony that the 68073 latex was not the best latex "for relaxation specifically" and that there were "other reasons" for using this particular latex, i.e., reasons related to production details, including the fact that large quantities of 68073 latex were already on hand at the

---

<sup>2</sup> Also, the fact that Mr. DeBecker identified "latex 68073" in this recipe does not evidence that this latex was preferred. Instead, it only identifies which latex was used in a *particular experiment*. [A8869-A8870 (640:21 - 641:6)].

manufacturing plant. [A116] (citing DeBecker, Tr. 702:6 -703:4, 85 1:7 - 852:5). And notably, the ALJ made this determination after having had the opportunity to receive and consider testimony from Mr. DeBecker and finding him to be “an extremely credible and honest witness.” [A126]. Such a determination thus should not be reversed. *See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, No. 2007-1448, 2008 WL 3891543, at \*6 (Fed. Cir. Aug. 25, 2008).

In criticizing the ALJ’s determination that there was not a best mode violation, Intervenors incorrectly state that Mr. DeBecker’s reasons for using 68073 latex were reasons “in addition” to the alleged fact that it results in a better glove. *See* Int. Br. at 51-52. Relying on this misstatement, Intervenors then attack the purported reasons “in addition” as irrelevant. *Id.* at 52. This straw-man argument should be rejected for two reasons. Foremost, Mr. DeBecker’s actual testimony is that he chose to use 68073 “for other reasons,” *not* reasons in addition to the alleged fact that it results in a better glove as Intervenors argue. [A8885 (702:6 - 703:4)].<sup>3</sup> Second, the evidence discussed above establishes that Mr. DeBecker did not believe that this latex would result in a glove having better

---

<sup>3</sup> Intervenors also incorrectly state that the “inventors believed that 68073 was a key to their invention.” *See* Int. Br. at 20. Yet nothing in the testimony Intervenors cite [A8881 (687:8 - 688:16)] supports this statement. Instead, Mr. DeBecker is merely clarifying that the latex 68073 was typically used for unsupported gloves and that -- consistent with this latex being on hand in the manufacturing facility -- Mr. DeBecker used this latex when making an unsupported glove. [A8881 (687:8 - 688:16)]. He did not say that the 68073 latex was “key” as Intervenors misstate.

relaxation properties. [A8882 (686:3-5, 689:13-18, 691:7-11, 691:19-25), A8885 (702:16 - 703:4), A8922 (851:1 - 852:5; 851:20-25)]. And critically, Intervenors have failed to present any evidence whatsoever that 68073 latex would actually result in a glove having better relaxation properties as compared to other latexes.

Intervenors also criticize the ALJ for not addressing the *Gypsum* decision or the unpublished *TALtech* decision in his Initial Determination. Int. Br. at 52-54 (citing *U.S. Gypsum Co. v. Nat'l Gypsum Co.*, 74 F.3d 1209 (Fed. Cir. 1996) and *TALtech Ltd. v. Esquel Apparel, Inc.*, No. 2007-1506, 2008 WL 2165996 (Fed. Cir. 2008))). More particularly, Intervenors rely on these decisions to argue that Tillotson was required to “disclose the trade name” of what Intervenors allege to be the best or “preferred ingredient,” i.e., Reichhold 68073. *Id.* at 54. But in both *Gypsum* and *TALtech*, the trade-name ingredients at issue were found to be critical to practicing the invention. *See Gypsum Co.*, 74 F.3d at 1212-13; *TALtech Ltd.*, 2008 WL 2165996 at \*3-4. In *Gypsum*, for example, the patentee considered a particular brand of perlite known as “Sil-42” to be “essential to improving the invention” at the time of the invention. *Gypsum Co.*, 74 F.3d at 1213. Sil-42 also was “not selected as a matter of commercial expediency,” but rather because of its nature and quality as a particular perlite. *See id.*; *see also BayerAG v. Schein Pharm., Inc.*, 301 F.3d 1306, 1317-18 (Fed. Cir. 2002) (distinguishing *Gypsum*). In fact, the patentee had admitted that perlites other than Sil-42 were “not acceptable.” *Gypsum Co.*, 74 F.3d at 1213. The *Gypsum* court thus concluded that

Sil-42 was the best mode and that the patentee failed to disclose Sil-42 as a critical ingredient. *Id.* at 1213-14. Because the patentee did not know the composition of Sil-42 or how it was made, the court noted that the patentee was required to have disclosed the supplier and trade name to comply with the best mode requirement. *Id.* at 1214.

Similarly, the patentee in *TALtech* considered a particular bonding element known as Vilene SL33 to be an “integral part” of the invention. *TALtech Ltd.*, 2008 WL 2165996 at \*3. The patentee also “settled on” Vilene SL33 after specifically experimenting with different bonding elements and determining that Vilene SL33 “worked best at the time of [the patentee’s patent] application.” *Id.* The Federal Circuit thus refused to disturb the district court’s ruling that the patentee believed Vilene SL33 to be the best mode and therefore should have disclosed this key ingredient in his patent. *Id.* at \*3-4.

Here, Intervenor’s argument that Tillotson failed to “disclose the trade name” of Reichhold 68073 hinges on their allegation that Mr. DeBecker believed that this latex was a better or “preferred ingredient” for the manufacture of a relaxing glove, which is not the case. Indeed, unlike the Sil-42 perlite in Gypsum or the Vilene SL33 material in *TALtech Ltd.*, there is no evidence that Tillotson believed that Reichhold 68073 was “essential to” or an “integral part of” the invention. *See Gypsum Co.*, 74 F.3d at 1213; *TALtech Ltd.*, 2008 WL 2165996 at \*3. Instead, the evidence establishes that, at the time of the invention, Mr.

DeBecker believed that both Reichhold 68073 and 68074 produced suitable relaxing gloves and therefore that one was no better than the other when producing the invention of the Reissue Patent. [A8885; A9114]; *see also* [A6694-A6695 at n.6 and n.7] (distinguishing *Gypsum* and *TALtech*). Thus, the ALJ properly concluded that there was no best mode violation concerning the identification of Reichhold brand 68073 latex. [A111-A1117]. As such, there was no need for the ALJ to address either the *Gypsum* and *TALtech* decisions or Intervenor's incorrect arguments relying on these decisions.

**2. The ALJ Properly Concluded That Intervenor's Failed To Establish That The Written Description Does Not Disclose The Best Mode.**

The ALJ also concluded that, even if the inventors subjectively preferred a particular nitrile latex for creating a relaxing glove, Intervenor's did not establish by clear and convincing evidence that the written description fails to disclose the best mode of practicing the claimed invention. [A115-A117]; *Bayer*, 301 F.3d at 1320. This prong of the best mode requirement focuses on "the scope of the claim and the level of one skilled in the art." *Id.*; *see also id.* at 1315 ("the best mode disclosure requirement only refers to the invention defined by the claims"). The '616 Patent does not claim a particular type of nitrile rubber or a manner of making a particular nitrile rubber. Instead, it claims "a closely fitting glove comprising a layer of elastomeric material (a) comprising nitrile butadiene rubber. . . ."

[A739(6:33-50)]. The specification identifies a formulation for such a glove that identifies carboxylated nitrile butadiene rubber as one of the starting materials used in the production of the claimed glove. [A739] at col. 5:35-45; [A8885 (702:16-22); A741-A746; A735-A740; A9705-A9709 at Q&A 22-23; A9769 at Q&A 99-101].

The disclosure of a routine or production detail, *i.e.*, a particular commercially available nitrile latex, is not required because such information is “readily apparent to one skilled in the art.” *Eli Lilly*, 251 F.3d at 963 (citing *Young Dental*, 112 F.3d at 1143). Here, the specification discloses the use of nitrile butadiene rubber (“NBR”), and the evidence establishes that one of ordinary skill in the art would have known of various types of commercially available NBR latexes at the time that the application was filed. [A738-A739 (4:65 – 5:53); A9775 at Q&A 116; A9793 at Q&A 348; A9794 at Q&A 352-356; A9797; A9798; A9800; A9802; A9805; A9808; A9114 (1470:25 - 1471:14)]. Thus, the selection of a particular type of NBR latex was a routine production detail outside of the ambit of the best mode requirement. *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1223 (Fed. Cir. 2006); *Eli Lilly*, 251 F.3d at 963; *Young Dental*, 112 F.3d at 1144. Intervenors’ authority to the contrary is inapposite. For example, Intervenors rely heavily on *Spectra-Physics Inc. v. Coherent, Inc.*, 827 F.2d 1524 (Fed. Cir. 1987), wherein the court found that the method developed by

inventor was “necessary to . . . the invention.” *Id.* at 1535-37. In contrast to the facts in *Spectra-Physics*, Mr. DeBecker did not determine that a particular type of NBR latex was necessary to the claimed invention -- a relaxing glove. *See* discussion above; [A8882; A8885].


Recognizing that, among other things, the ‘616 Patent specification “lays out a specific formula for one of ordinary skill in the art to practice the invention,” the ALJ properly concluded that the “evidence does not clearly and convincingly show that the written description failed to disclose the best mode such that one of ordinary skill could not practice it.” [A116]. Indeed, as the ALJ reiterated, the claims are directed to a glove “comprising nitrile rubber.” *Id.* Nothing about the ‘616 Patent requires a particular brand of latex such as Reichhold 68073. Any preference for this latex did not relate to the glove’s relaxing quality as discussed above, but to “other reasons” such as ready availability and commercial convenience. *See id.* at 94-96. The ALJ recognized this fact and thus properly concluded that there was no need to identify this particular brand of latex in the patent.

Lastly, Intervenor’s argument that the ALJ confused the enablement requirement with the best mode is misplaced. [A8206-A8207]. The Federal Circuit has made plain that the second inquiry in the best mode analysis is – whether the written description disclosed the best mode such that one of ordinary

skill in the art could practice it. *Eli Lilly*, 251 F.3d at 963; *Young Dental*, 112 F.3d at 1144. Here, the best mode for practicing the invention requires using NBR, not a particular brand of NBR such as 68073. [A739 at col. 5:35-45; A8885 (702:16-22); A741-746; A735-A740; A9705-9709 at Q&A 22-23; A9769 at Q&A 99-101]. The ALJ recognized this fact and that the '616 Patent discloses this best mode by "list[ing] carboxylated nitrile butadiene rubber as its first ingredient." [A116]. Thus, in addition to determining that the 68073 latex is not required to practice the invention, the ALJ concluded as fact that the best mode – using carboxylated nitrile butadiene rubber – was properly disclosed. *Id.*

Dated: August 31, 2009

Respectfully submitted,

  
\_\_\_\_\_  
William D. Belanger  
Gregory C. Dorris  
PEPPER HAMILTON, LLP

*Attorney for Defendant Appellant*

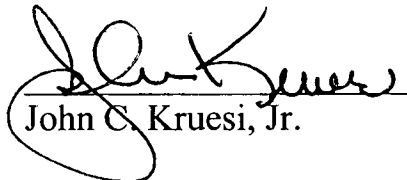
**DECLARATION OF AUTHORITY PURSUANT TO  
28 U.S.C. § 1746 AND FEDERAL CIRCUIT RULE 47.3(d)**

I, John C. Kruesi, Jr, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

I am an employee of Counsel Press. Counsel Press was retained by Attorneys for Appellant to print the enclosed documents.

The attached Reply Brief for Appellant has been submitted to Counsel Press, by the above attorneys, electronically and/or has been reprinted to comply with the Court's rules. Because of time constraints and the distance between counsel of record and Counsel Press, counsel is unavailable to provide an original signature, in ink, to be bound in one of the briefs. Pursuant to 28 U.S.C. §1746 and Federal Circuit Rule 47.3(d), I have signed, or resigned the documents for William D. Belanger, with actual authority on his behalf as an attorney appearing for the party.

August 31, 2009

  
John C. Kruesi, Jr.