

Recent Federal Circuit Caselaw Developments - September 2019

Presented By: Ashley Yeum

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Christopher Wheeler

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*WRITTEN DESCRIPTION
("SUBSTANTIALLY EQUIVALENT" DISCLOSURE)*

- *NALPROPION PHARMACEUTICALS v. ACTAVIS LABORATORIES*

Presented by: Ashley Yeum

Fed. Cir., August 15, 2019; [Lourie](#), Prost & Wallach
Appealed from D. Del. (Andrews, J.)

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NALPROPION PHARMACEUTICALS v. ACTAVIS LABORATORIES

**Factual/Procedural
Background**

- Nalpropion is owner of three Orange Book listed patents (the '111, '626, and '195 patents) covering weight loss drugs (Contrave®).
- Hatch-Waxman litigation triggered by ANDA filed by Actavis.
- Actavis argued for **(1) invalidity of the '195 patent due to lack of written description**, and (2) invalidity of the '111 and '626 patents due to obviousness.
- District court affirmed validity of all three patents.
- Federal Circuit **affirmed the district court on (1)**, but reversed on (2).

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NALPROPION PHARMACEUTICALS v. ACTAVIS LABORATORIES

Claim Language (the '195 patent)

11. A method of treating overweight or obesity having reduced adverse effects comprising orally administering daily about 32 mg of naltrexone and about 360 mg of bupropion, or pharmaceutically acceptable salts thereof, to a person in need thereof...wherein the naltrexone or pharmaceutically acceptable salt thereof is administered as a sustained release formation, and wherein said sustained release formulation of naltrexone has an *in vitro* naltrexone dissolution profile **in a dissolution test of USP Apparatus 2 Paddle Method at 100 rpm** in a dissolution medium of water at 37 °C of:

- between 39% and 70% of naltrexone released in one hour;
- between 62% and 90% of naltrexone released in two hours; and
- at least 99% in 8 hours...

"USP Apparatus 2"
(paddle method)

Actavis challenged written description support for the claim because the specification does not report dissolution testing results in accordance with USP Apparatus 2 (paddle method), but rather reports results obtained using a different method, i.e., USP Apparatus 1 (basket method).

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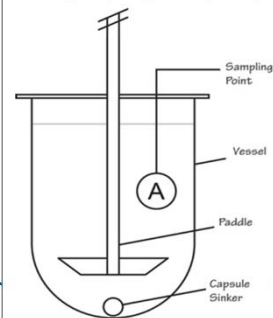
NALPROPION PHARMACEUTICALS v. ACTAVIS LABORATORIES

Paddle Method v. Basket Method

Apparatus 2 - Rotating Paddle

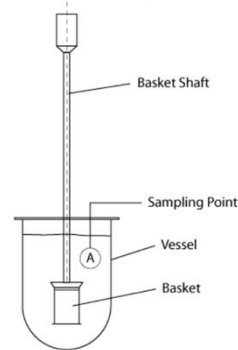
The Paddle Test

The Rotating Paddle, although Method 2, is actually the



Apparatus 1 - The Rotating Basket

Apparatus 1 - The Rotating Basket



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NALPROPION PHARMACEUTICALS v. ACTAVIS LABORATORIES

Prosecution History / Specification

- The claim language at issue (specifying the USP Apparatus 2 paddle method) was added in the last amendment before the application was allowed. The claim previously recited using a "standard" dissolution test. The Examiner cited this in the reasons for allowance.
- In the response, Applicant said that the amendment is supported by paragraph [0044] of the specification.

[0044] The term "release rate", as used herein, has its ordinary meaning as understood by those skilled in the art and thus includes, by way of non-limiting example, a characteristic related to the amount of an active ingredient released per unit time as defined by in vitro or in vivo testing. **An in vitro release rate is determined by a "standard dissolution test."** conducted according to United States Pharmacopeia 24th edition (2000) (USP 24), pp. 1941-1943, **using Apparatus 2 described therein at a spindle rotation speed of 100 rpm and a dissolution medium of water, at 37.degree. C., or other test conditions substantially equivalent thereto.**

This paragraph does not clearly link the claimed specific dissolution values to the USP Apparatus 2 paddle method.

NALPROPION PHARMACEUTICALS v. ACTAVIS LABORATORIES

Prosecution History / Specification

Example 3 dissolution profiles (shown in Table 10 and Figure 3 below), along with Table 5 (not shown), support the claimed measurement values. The specification is silent as to whether the data were obtained using USP 1 or USP 2. All other examples of dissolution profiles disclosed in the specification (for different compounds) use USP 1.

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TABLE 10	
Dissolution Data for Naltrexone-Bupropion Tablets	
Time (Hours)	Naltrexone Released (Wt %)
0	0
0.5	48
1	67
2	85
4	95
8	99

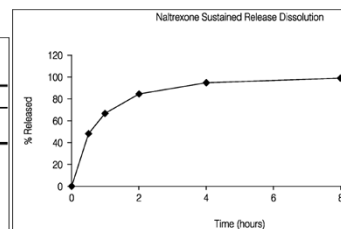


FIG. 3

NALPROPION PHARMACEUTICALS v. ACTAVIS LABORATORIES

Prosecution History / Specification

- Specification includes general descriptions of sustained release in reference to the "standard" dissolution test (disclosed as USP 2).

The amount of the sustained-release carrier composition may be effective to provide an in vitro release rate of the naltrexone of less than about 90%, or less than about 80%, in about 2 hours. The amount of the sustained-release carrier composition may be effective to provide an in vitro release rate of the naltrexone of less than about 98% in about 4 hours. The amount of the sustained-release carrier composition may be effective to provide an in vitro release rate of the naltrexone of less than about 80% or than about 70% in about 1 hour. In vitro release rate is determined by a standard dissolution test as described above.

This paragraph, however, does not explicitly support all of the claimed range values (e.g., the lower limits and the range for 8 hour dissolution). These values are only explicitly supported by the dissolution testing results in the examples in the specification.

NALPROPION PHARMACEUTICALS v. ACTAVIS LABORATORIES

Issue Discussion

- **Actavis argued** that the claim requiring specific dissolution characteristics using the specific testing method, i.e., USP 2, does not have adequate written description support.
- **District Court found that:**
 - (1) "whether the dissolution data reported in the specification was obtained using the basket method or the paddle method is not relevant to whether the inventors had possession of the invention."
 - (2) the two dissolution testing methods were "substantially equivalent."
- **Federal Circuit (majority) agreed with both (1) and (2), but Prost disagreed with a dissent.**

NALPROPION PHARMACEUTICALS v. ACTAVIS LABORATORIES

Issue Discussion (Majority)

- Inventive concept is the sustained release of carrier to treat overweight or obesity, not the specific dissolution testing method.
 - "It is important to take note of the *peculiarity* of claim 11, which begins clearly enough by reciting a method of treating overweight or obesity by carrying out the specific, positive steps of administering a formulation of specific amounts of sustained-release naltrexone and bupropion in twice a day...dissolution profile...does not relate to the operative steps."
 - Not that peculiar to recite product features in therapeutic method claims?
- "irrespective of the method of measurement used, the specification shows that the inventors possessed the invention of treating overweight or obesity with naltrexone and bupropion in particular amounts and adequately described it."
- "It is not necessary that the exact terms of a claim be used *in haec verba* in the specification, and equivalent language may be sufficient."

NALPROPION PHARMACEUTICALS v. ACTAVIS LABORATORIES

Issue Discussion (Majority)

- Written description = a question of fact (deference to lower court)
 - District court performed its fact finding function when weighting credibility of expert testimonies and deciding that Nalpropion's expert (arguing that a POSITA would consider USP 1 and USP 2 to be substantially equivalent) is more credible than Actavis' expert (arguing that a POSITA would know that the two tests are substantially different and would produce different results).
 - "The district court was convinced by its fact findings that Actavis had not proven by clear and convincing evidence that...patent is invalid for lack of adequate written description. While as a general matter written description may not be satisfied by so-called equivalent disclosure, in this case, buttressed by the district court's fact-finding...we affirm."

NALPROPION PHARMACEUTICALS v. ACTAVIS LABORATORIES

Issue Discussion (Dissent)

- **The USP 2 clause is limiting.**
 - Clearly, a property of claimed naltrexone formulation.
 - Applicant overcame a rejection relying on USP 2 clause.
- **The majority's "substantially equivalent" rule is squarely inconsistent with the precedent.**
 - A substantially equivalent disclosure, even if it would render the claim limitation obvious, cannot satisfy the written description requirement. *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 589 F.3d 1336, 1352 (Fed. Cir. 2010).
- **District court clearly erred in finding that the two tests are substantially equivalent.**
 - The record contains no evidence showing that the two methods produce the same results (pointing out that even Nalpropion's expert never testified that the two tests would produce the same results).

Questions?



TRADEMARK REFRESHER: BACK TO BASICS

- *"The" Trademark Application of The Ohio State University*

Presented by: Jason French

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Trademark Basics

TSDR	ASSIGN Status	TTAB Status	(Use the "Back" button of the Internet Browser to return to TESS)
<h1>THE</h1>			
Word Mark	THE		
Goods and Services	IC 025. US 022 039. G & S. Clothing, namely, t-shirts, baseball caps and hats. FIRST USE: 20050800. FIRST USE IN COMMERCE: 20050800		
Standard Characters Claimed			
Mark Drawing Code	(4) STANDARD CHARACTER MARK		
Serial Number	88571984		
Filing Date	August 8, 2019		
Current Basis	1A		
Original Filing Basis	1A		
Owner	(APPLICANT) The Ohio State University state university OHIO 190 N. Oval Mall Columbus OHIO 43210		
Attorney of Record	Samantha M. Quimby		
Type of Mark	TRADEMARK		
Register	PRINCIPAL		
Live/Dead Indicator	LIVE		

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University of Michigan
@UMich

25.1K 3:28 PM - Aug 14, 2019

6,313 people are talking about this




Ohio University
@ohiou

Good morning from THE first university in the state of Ohio. ☺

10.6K 9:20 AM - Aug 14, 2019

2,639 people are talking about this




Buffalo Wild Wings
@BWwings

We stand with THE Ohio State University in their quest to trademark "THE"

5,555 4:55 PM - Aug 14, 2019

772 people are talking about this




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Trademark Basics

What is a Trademark?

- USPTO generally defines a trademark as a word, phrase, symbol, or design, or a combination of these elements, that identifies and distinguishes the source of one party's goods from those of others.
- A service mark is the same as a trademark except that it identifies and distinguishes the source of a service rather than goods.



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Trademark Basics

Types of Marks

- Arbitrary or Fanciful



- Suggestive



Trademark Basics

Types of Marks

- Descriptive



- Generic



Trademark Basics

Potential Problems Application

- "The" is not being used as a trademark
 - Trademarks identify the source goods



Trademark Basics

Potential Problems with Application

- No Secondary Meaning
 - No evidence consumers associate "The" with any particular source of products



Trademark Basics

Potential Problems with "The"

- Application for "The" is likely to be rejected
- But will have an opportunity to fix

Trademark Basics

Contrasting Case



Trademark Basics

Contrasting Case

- In 2004, Donald Trump filed an application to trademark the phrase "You're fired!" for use on clothing, games, and casino services
- This phrase was used by Donald Trump on NBC's "The Apprentice"
- At its peak, the show had 28 million viewers

Trademark Basics

Contrasting Case

- Secondary Meaning
 - Phrase became readily identifiable with him
- Application was ultimately rejected because it sounded too similar to the board game "You're Hired"

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Questions?



Personal Jurisdiction under F.R.C.P. 4(k)(2)

- *GENETIC VETERINARY SCIENCES, INC. v. LABOKLIN GMBH & CO. KG*

Presented by: James F. Potts

Fed. Cir., August 9, 2019; [Wallach](#), Hughes & Stoll
Appealed from E.D. Va. (Morgan, J.)

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GENETIC VETERINARY SCIENCES, INC. v. *LABOKLIN GMBH & CO. KG*

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Factual Background

- The University of Bern, an agent of the Swiss Confederation, owns a U.S. patent directed to the use of in vitro methods for genotyping dogs in order to discover whether a dog carries the genetic disease HNPk by testing for mutations in the SUV39H2 gene.
- The University granted an exclusive license of its patent to LABOKLIN, a foreign company whose principal place of business is in Germany.

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*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Factual Background

- The licensing agreement:
 - required consent from both parties before sending a cease-and-desist letter to potential infringers;
 - required LABOKLIN to commercialize the invention in North America within a given timeframe; and
 - stated that, should an infringing activity continue beyond a predetermined period, LABOKLIN may sue for infringement if the University declines to bring suit and says so in writing.

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*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Factual Background

- LABOKLIN subsequently entered into two sublicensing agreements with US companies in California and Michigan.

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*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Factual Background

- Genetic Veterinary Sciences d/b/a Paw Print Genetics ("PPG") is a Washington corporation that offers genetic testing for mutations that cause diseases in dogs, including a test for mutation in the SUV39H2 gene.
- PPG allows dog owners "from all over the world" to send in DNA for testing.

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*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Procedural Background

- With the University's consent, LABOKLIN sent a cease-and-desist letter to PPG, alleging infringement of claims 1-3 of the patent and demanding that PPG either cease its activities or enter into a sublicensing agreement with LABOKLIN.
- In response, PPG filed suit in the Eastern District of Virginia, seeking a declaratory judgment that the asserted claims are patent-ineligible under 35 U.S.C. §101.

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*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Procedural Background

- LABOKLIN moved to dismiss the suit, arguing lack of personal jurisdiction.
- LABOKLIN also filed counterclaims, alleging infringement of the patent.
- Because PPG stipulated to infringement, the only issues at trial were jurisdiction and PPG's invalidity defense.

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*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Procedural Background

- The district court denied the motion to dismiss, finding that the court had personal jurisdiction.
- After the close of evidence, but before the case was submitted to a jury, PPG moved for JMOL that the claims are invalid under 35 U.S.C. §101. The district court granted PPG's motion, holding the claims were directed to patent-ineligible subject matter.
- LABOKLIN and the University appealed the decision to the Federal Circuit.

*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Federal Circuit Holding

- The Federal Circuit affirmed the district court's decision, ruling that the court had personal and subject-matter jurisdiction and that the JMOL holding the claims to be invalid was proper.

*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Issue Discussion: Personal Jurisdiction

Under the Federal Circuit's interpretation of F.R.C.P. 4(k)(2), personal jurisdiction is established if:

- (1) the plaintiff's claim arises under federal law,
- (2) the defendant is not subject to jurisdiction in any state's courts of general jurisdiction, and
- (3) the exercise of jurisdiction comports with due process.

*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Issue Discussion: Personal Jurisdiction

- As the parties did not dispute the district court's findings that PPG's claim arose under federal law and that LABOKLIN was not subject to jurisdiction in any state's courts of general jurisdiction, the only relevant question was whether exercise of jurisdiction complied with due process.
- In order to comply with due process, a nonresident defendant must have "certain minimum contacts with [the United States] such that maintenance of the suit does not offend traditional notions of fair play and substantive justice."

*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Issue Discussion: Personal Jurisdiction

The Federal Circuit uses a three-pronged test to decide whether an assertion of personal jurisdiction complies with due process:

- (1) whether the defendant purposefully directed its activities at residents of the forum;
- (2) whether the claim arises out of or relates to the defendant's activities with the forum; and
- (3) whether assertion of personal jurisdiction is reasonable and fair.

*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Issue Discussion: Personal Jurisdiction

- In finding that the first two prongs are met, the Federal Circuit evaluated the cease-and-desist letter and LABOKLIN's sublicensing agreements in the U.S.
 - The cease-and-desist letter was sent to PPG's U.S. address and threatened PPG's domestic business by accusing PPG of committing infringement and demanding that it cease its testing or enter into a sublicensing agreement with LABOKLIN.

*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Issue Discussion: Personal Jurisdiction

- And "PPG's claim for declaratory judgment arises out of or relates to LABOKLIN's patent sublicensing and its enforcement activities in the United States pursued in [the] cease-and-desist letter from LABOKLIN's counsel."
- The Federal Circuit thus held that "the [first two prongs] are met based upon LABOKLIN's cease-and-desist letter together with its commercial sublicenses."

*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Issue Discussion: Personal Jurisdiction

In evaluating the third prong, the Federal Circuit determines whether personal jurisdiction is "reasonable and fair" based on five considerations:

- (1) The burden on the defendant;
- (2) The forum state's interest in adjudicating the dispute;
- (3) The plaintiff's interest in obtaining convenient and effective relief;
- (4) The interstate judicial system's interest in obtaining the most efficient resolution of controversies; and
- (5) The shared interest of the several States in furthering fundamental substantive social policies.

*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Issue Discussion: Personal Jurisdiction

- PPG's interest in determining its liability and the United States' interest in enforcing federal patent laws outweighed any burden that litigating in the U.S. would place on LABOKLIN.
- The court stated that "exercising personal jurisdiction over LABOKLIN is 'reasonable and fair' because LABOKLIN has purposefully availed itself of the benefits and protection of U.S. laws through its commercial sublicensing as well as its enforcement of a U.S. patent."

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*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Issue Discussion: Personal Jurisdiction

- LABOKLIN argued that "merely sending a [cease-and-desist] letter does not create specific personal jurisdiction over LABOKLIN," citing *Red Wing Shoe* and *Avocent*.
- The court dismissed this line of reasoning, reiterating that "*Red Wing Shoe* and *Avocent* did not create such a bright-line rule, and doing so would contradict the Court's directive to 'consider a variety of interests' in assessing whether jurisdiction would be fair."

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*GENETIC VETERINARY SCIENCES, INC. v.
LABOKLIN GMBH & CO. KG*

Conclusion

- The court thus held that personal jurisdiction was proper over LABOKLIN.
- In a separate analysis, the Federal Circuit also affirmed the district courts ruling that the claims of the patent were patent-ineligible under 35 U.S.C. §101.

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Questions?



Claim Construction & 35 U.S.C §112(f)

- *MTD Products Inc. v. Andrei Iancu, Director of USPTO*

Presented by: Patrick Gildea

Fed. Cir., August 12, 2019; Reyna, Taranto & Stoll

Appealed from PTAB

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MTD Products Inc. v. Iancu

Background

- MTD owns a patent that is directed to a steering and driving system for zero-turn-radius (ZTR) vehicles, which allow the ZTR vehicle to mimic the forward and backwards movements of a conventional automobile.
- The Toro Company sought *inter partes* review of MTD's patent, which was instituted by the PTAB.
- During the IPR proceeding, MTD took the position that the claim term "mechanical control assembly" is a means-plus-function term, and that the prior art did not disclose the corresponding structure for the "mechanical control assembly."

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MTD Products Inc. v. Iancu

Representative Claim 1 Recites In Part:

a mechanical control assembly coupled to the left and right drive units that is configured to actuate the left and right drive units based on a steering input received from the steering device and a speed input received from the speed control member;

the mechanical control assembly being configured such that if the speed control member is shifted from: (a) a forward position in which the left drive wheel is rotating in a forward direction at a first forward speed and the right drive wheel is rotating in a forward direction at a second forward speed that is less than the first forward speed as a result of the steering device being in a first right turn position to (b) a reverse position while the first right turn position of the steering device is maintained, then the left drive wheel will rotate in a reverse direction at a first reverse speed and the right drive wheel will rotate in a reverse direction at a second reverse speed that is less than the first reverse speed.

MTD Products Inc. v. Iancu

MTD's Prosecution History

- In a 35 U.S.C. §102(b) rejection, the Examiner asserted that the functional language associated with the claim term "mechanical control assembly" represented intended use, and thus did not have patentable weight.
- In response, MTD made statements in their traversal that included (emphases in original):
 - "the claim language at issue concerns the **configuration** of the claimed mechanical control assembly," and
 - "the claimed configuration **is** indeed structural."

MTD Products Inc. v. Iancu

PTAB's Ruling on Claim Construction

- Initially, the PTAB agreed with MTD's position that "mechanical control assembly" was a means-plus-function term because, when viewed in isolation, the genericness of "mechanical control assembly" bears similarity to other nonce terms that have been interpreted under §112(f), such as "mechanism," "device" and "member."
- However, the PTAB ruled that "mechanical control assembly" did not invoke interpretation under §112(f) because:
 - MTD's specification specifically disclosed a ZTR control assembly, which the PTAB construed as corresponding to the claimed "mechanical control assembly," and
 - MTD's statements during prosecution of their patent.

MTD Products Inc. v. Iancu

PTAB's Ruling on Claim Construction

- In the Final Written Decision, the PTAB held that a person of ordinary skill in the art would understand that the claim term "mechanical control assembly" denotes structure because "the specification illustrates and describes the specific structure that makes up the ZTR control assembly, and how it connects to and operates with other components."
- The PTAB also held that the statements made by MTD during prosecution presented strong evidence in favor of "mechanical control assembly" being construed as a structural term, and not a means-plus-function term.

MTD Products Inc. v. Iancu

Issue on Appeal

- Did the PTAB err by construing "mechanical control assembly" as a structural term, and not a means-plus-function term?

MTD Products Inc. v. Iancu

Issue on Appeal

- Did the PTAB err by construing "mechanical control assembly" as a structural term, and not a means-plus-function term?

Yes - reversed and remanded to the PTAB

MTD Products Inc. v. Iancu

Federal Circuit's Holding

- The Federal Circuit ruled that the specification does not demonstrate that MTD intended to act as their own lexicographer with respect to "mechanical control assembly," and that the PTAB erred by conflating the corresponding structure in the specification with a structural definition for "mechanical control assembly."
- Specifically, the Federal Circuit determined that the specification does not expressly define the nonce term "mechanical control assembly" as the "ZTR control assembly" of the preferred embodiment, and that the specification does not even refer to a "mechanical control assembly."

MTD Products Inc. v. Iancu

Federal Circuit's Holding

- The Federal Circuit also ruled that the PTAB erred by misinterpreting statements made by MTD during prosecution.
- The Federal Circuit determined that MTD's statements were not made within the context of §112(f), and MTD did not clearly disclaim interpretation under §112(f).
- Moreover, the Federal Circuit held that the functional language associated with a means-plus-function term has patentable weight because the means-plus-function features connote structure (i.e., based on the corresponding structure and equivalents thereof).

MTD Products Inc. v. Iancu

Practice Tip for Prosecution

- For claims in which functional language associated with a respective means-plus-function term is interpreted by the Examiner as representing intended use:
 - assert that the respective means-plus-function term invokes interpretation under §112(f) and that the functional language associated with the means-plus-function term has patentable weight based on the corresponding structure and equivalents thereof (*which are presumably adequately disclosed in the specification*).

Questions?



DOCTRINE OF EQUIVALENTS

- *ELI LILLY AND COMPANY v. HOSPIRA, INC.*
- *ELI LILLY AND COMPANY v. DR. REDDY'S LABORATORIES, LTD.*

Presented by: Chris Wheeler

Fed. Cir., August 9, 2019; [Lourie](#), Moore & Taranto
Appealed from S.D. Ind. (Judge Pratt)

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ELI LILLY v. HOSPIRA *ELI LILLY v. DR. REDDY'S*

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Case History

- Lilly markets the compound pemetrexed in the form of a disodium salt as Alimta®, which is indicated for treating certain types of non-small cell lung cancer and mesothelioma, and owns a patent directed to the same.
- Pemetrexed is an antifolate, which is a class of molecules that essentially mimic folic acid and inhibit nucleotide synthesis.
- Lilly's patent is directed to an improved method of treatment with pemetrexed disodium through supplementation with a methylmalonic acid lowering agent and folic acid, which lessens antifolate toxicity without sacrificing efficacy.

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ELI LILLY v. HOSPIRA
ELI LILLY v. DR. REDDY'S

Case History

- Hospira and Dr. Reddy's both submitted New Drug Applications relying on Lilly's clinical data for pemetrexed disodium but seeking to market different pemetrexed salts – pemetrexed ditromethamine.
- Lilly then sued both Hospira and Dr. Reddy's for infringement of its patent.
- The district court held that Hospira's and Dr. Reddy's NDAs both infringed Lilly's patent under the Doctrine of Equivalents.
- The Federal Circuit affirmed the district court's finding of infringement under DOE.

ELI LILLY v. HOSPIRA
ELI LILLY v. DR. REDDY'S

Issue Background

- In prosecution of a parent application, Lilly narrowed the independent claims to recite "pemetrexed disodium" instead of the broader class "antifolate" to overcome prior art rejections.
- In its remarks, Lilly asserted that the amendment overcame the rejections because the prior art does not disclose pemetrexed disodium (in one rejection) or vitamin supplementation (in another rejection).
- The parent application issued as a patent and the application relating to the patent at issue was filed with a representative independent claim reciting the narrower recitation of pemetrexed disodium (*i.e.*, "administration of pemetrexed disodium").

ELI LILLY v. HOSPIRA
ELI LILLY v. DR. REDDY'S

Issue Background

- In holding that Hospira's and Dr. Reddy's NDAs both infringed Lilly's patent under the DOE, the district court found that:
 - Prosecution history estoppel does not bar Lilly from asserting that the proposed pemetrexed ditromethamine product would infringe through DOE because the reason for Lilly's amendment was to distinguish other antifolates and was therefore only tangential to pemetrexed ditromethamine, and
 - The proposed product would be administered in a manner that would meet the "administration of pemetrexed disodium" under DOE regardless of the "differences in chemical properties between pemetrexed disodium and pemetrexed ditromethamine."

ELI LILLY v. HOSPIRA
ELI LILLY v. DR. REDDY'S

Issue Background – DOE Refresher

- Prosecution history estoppel arises when a patent applicant narrows the scope of his claims during prosecution for a reason "substantial[ly] relating to patentability." See generally *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366–67 (Fed. Cir. 2003) (en banc) ("*Festo X*").
- Such a narrowing amendment is presumed to be a surrender of all equivalents within "the territory between the original claim and the amended claim," but the presumption is overcome if the patentee can show the applicability of one of the few exceptions identified by the Supreme Court. *Festo VIII*, 535 U.S. at 740–41 (citing *Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136–37 (1942)).

ELI LILLY v. HOSPIRA
ELI LILLY v. DR. REDDY'S

Federal Circuit - Background

- Lilly did not dispute that the amendment in question was both narrowing and made for a substantial reason relating to patentability.
- Further, Lilly relied on only one exception to giving effect to the presumption as to the scope of surrender: that the rationale of its amendment “[bore] no more than a tangential relation to the equivalent in question.”
- Thus, the DOE issue turned on whether Lilly’s amendment narrowing “an antifolate” to “pemetrexed disodium” was only tangential to the accused compound— pemetrexed ditromethamine.

ELI LILLY v. HOSPIRA
ELI LILLY v. DR. REDDY'S

Federal Circuit – Appellants Arguments

- Appellants argued that Lilly failed to explain why it did not pursue a narrower amendment literally encompassing pemetrexed ditromethamine, and they emphasized the Federal Circuit’s own position that the tangential exception is “very narrow.”
- They argued that Lilly cannot be said to have “lacked the words to describe” pemetrexed ditromethamine because Lilly’s previous patents, as well as the European companion to the patent at issue, claimed pemetrexed salts generally and pemetrexed disodium in a dependent claim.
- They also asserted that the district court erred by focusing on whether Lilly actually needed to relinquish pemetrexed ditromethamine to overcome the rejection because “the tangential exception is not a patentee’s-buyer’s-remorse exception.”

ELI LILLY v. HOSPIRA
ELI LILLY v. DR. REDDY'S

Federal Circuit – Lilly's Arguments

- Lilly argued that the district court properly held that the reason for its amendment was to distinguish pemetrexed from antifolates generally and that the different salt type is a merely tangential change with no consequence for pemetrexed's administration or mechanism of action within the body.
- Lilly also contended that it is not barred from asserting the tangential exception simply because pemetrexed ditromethamine is within "the territory between the original claim and the amended claim."
- Finally, Lilly argued that Appellants' view that courts must "consider hypothetical alternative amendments" that would literally encompass the alleged equivalent "would eviscerate the tangentiality exception."

ELI LILLY v. HOSPIRA
ELI LILLY v. DR. REDDY'S

Federal Circuit - Findings

- The Federal Circuit agreed with Lilly finding that the Appellants' view of prosecution history estoppel, and the tangential exception in particular, was too rigid.
- The reason for Lilly's amendment was to narrow the original claim to avoid an anticipation rejection over art that merely disclosed treatments using methotrexate, which is a different antifolate.
- The particular type of salt to which pemetrexed is complexed relates only tenuously to the reason for the narrowing amendment, which was to avoid methotrexate.

ELI LILLY v. HOSPIRA
ELI LILLY v. DR. REDDY'S

Federal Circuit - Holding

- The Federal Circuit therefore held that Lilly's amendment was merely tangential to pemetrexed ditromethamine because the prosecution history, in view of the patent at issue itself, strongly indicated that the reason for the amendment was not to cede other, functionally identical, pemetrexed salts.
- The Federal Circuit found the prosecution history of the patent at issue instructive in this regard, noting that art cited in the parent application against "antifolates" was not never cited against "pemetrexed disodium" in the prosecution of the patent at issue.
- According to the Federal Circuit, this suggested that Lilly's amendment was prudential in nature and did not need or intend to cede other pemetrexed salts.

ELI LILLY v. HOSPIRA
ELI LILLY v. DR. REDDY'S

Federal Circuit - Holding

- Appellants' also insisted that the Federal Circuit has held that an applicant's remorse at ceding more claim scope than necessary is not a reason for the tangential exception to apply.
- While noting that this is generally true, the Federal Circuit opined that the reason for an amendment, where the tangential exception is invoked, cannot be determined without reference to the context in which it was made, including the prior art that might have given rise to the amendment in the first place.
- According to the Federal Circuit, it is unlikely that a competitor would have been "justified in assuming that if he made an equivalent pemetrexed salt, he would not infringe."

ELI LILLY v. HOSPIRA
ELI LILLY v. DR. REDDY'S

Federal Circuit - Holding

- The Federal Circuit also dispelled Appellants' suggestion that Lilly must prove that it could not have drafted a claim that literally encompassed pemetrexed ditromethamine because the notion is unsupported by Federal Circuit precedent on prosecution history estoppel.
- Lilly's burden was to show that pemetrexed ditromethamine was "peripheral, or not directly relevant," to its amendment, which it had done, according to the Federal Circuit.
- Quoting from *Festo*, the Federal Circuit noted "We do not demand perfection from patent prosecutors, and neither does the Supreme Court."

ELI LILLY v. HOSPIRA
ELI LILLY v. DR. REDDY'S

Federal Circuit - Holding

- Finally, Dr. Reddy's argued that Federal Circuit precedent squarely foreclosed Lilly's tangentiality argument, asking the Federal Circuit to hold that "where the reason for the amendment and the equivalent in question both relate to the same claim element, the tangential exception does not apply."
- The Federal Circuit declined noting that such a bright-line rule is both contrary to the equitable nature of prosecution history estoppel, as articulated in *Festo*, and inconsistent with the equitable spirit that animates the DOE.
- Instead, it reaffirmed that whether an amendment was merely tangential to an equivalent must be decided in the context of the invention disclosed in the patent and the prosecution history.

ELI LILLY v. HOSPIRA
ELI LILLY v. DR. REDDY'S

Federal Circuit - Holding

- The Federal Circuit explained that an amendment that narrows an existing claim element often evinces an intention to relinquish that claim scope.
- And that it is a powerful indication that an amendment was not merely tangential.
- But here, the Federal Circuit concluded that this consideration is not dispositive because the rest of the prosecution history, and the patent itself, showed that it is implausible that the reason for Lilly's amendment was to surrender other pemetrexed salts.

Questions?



PRODUCT DESIGN TRADE DRESS

- *CONVERSE, INC. v. INTERNATIONAL TRADE COMMISSION*

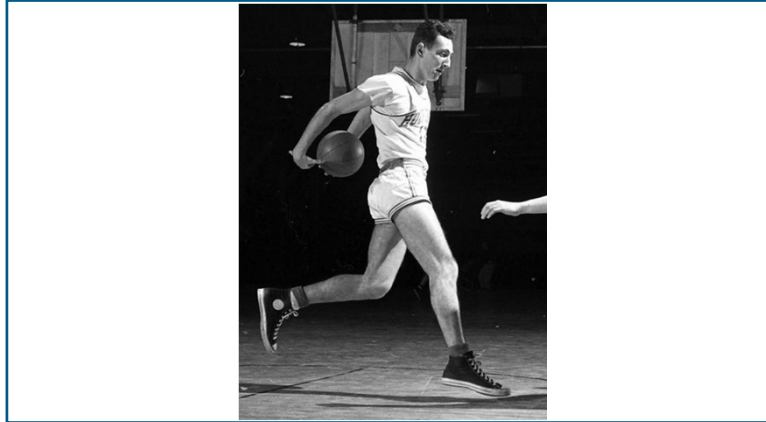
Presented by: Bill Utermohlen Fed. Cir., October 30, 2018; Dyk, Hughes, dissent: O'Malley
Appealed from I.T.C. (Bullock, A.L.J.)



Converse v. ITC



Converse v. ITC



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Converse v. ITC



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Converse v. ITC

Background

Converse Arc

- 1960s – 90% of NBA
- Early 1980s – 0% of NBA
- Became a popular style of sneaker
- 2003 Converse sold to Nike

Converse v. ITC

Trade Dress

Type of Trademarks

- Word Marks
- Logos
- Product packaging trade dress
- Product design trade dress

Converse v. ITC

Trade Dress

The 'trade dress' of a product is essentially its total image and overall appearance and may include features such as size, shape, color or color combinations, texture, graphics, or even particular sales techniques

Two Pesos (US 1992)

Converse v. ITC

Trade Dress

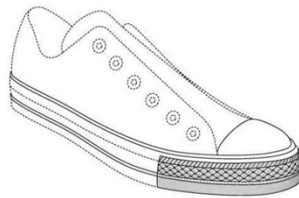
Elements

- Non-functional
- Distinctive, also known as Secondary Meaning
- Infringement = Likelihood of Confusion

Converse v. ITC

U.S. Trademark Registration No. 4,358,753
September 10, 2013

- 2 stripes on the midsole
- The toe cap
- Toe bumper featuring diamonds and line patterns



Converse v. ITC

Secondary Meaning

2 Kinds of Distinctiveness

- inherent distinctiveness
 - intrinsic nature identifies source
- acquired distinctiveness
 - public comes to recognize the product feature as source identifying

Converse v. ITC

Secondary Meaning

Wal-Mart (2000)

- Product design features are never inherently distinctive
- Public tends to assume they are just product features
- Secondary meaning must be proven

Converse v. ITC

Trade Dress

- Product design trade dress can be registered
- Secondary meaning must be shown (same as for a descriptive mark)
- PTO may accept 5 years substantial and exclusive use = secondary meaning
- If registered, registration is presumed valid = shifts burden of proof

Converse v. ITC

ITC Case

In 2014, Converse sued 32 parties in the ITC, seeking an exclusion order.

- 5 defaulted; 21 settled; about 6 defended

Issues include:

- Secondary meaning
- Infringement

Converse v. ITC

ITC Case

Initial Determination (ALJ)

1. Registered mark valid based on presumption.
2. Common law mark invalid – no secondary meaning.
3. Defendants infringe.

Converse v. ITC

ITC Case

Final Determination

1. Registered mark invalid – no secondary meaning.
2. Common law mark invalid.
3. If valid, would be infringed.

Converse v. ITC

Federal Circuit

Common law mark = ® mark

Only one mark – ® adds rights

Relevant date of rights

2003 – first infringement

2013 – registration

Converse v. ITC

Federal Circuit

- Mark must have secondary meaning before infringement
- Cannot rely *nunc pro tunc* on later ®
- As to registration, presumption of secondary meaning applies on date of issue

Converse v. ITC

Federal Circuit

Federal Circuit announced 6-factor test for secondary meaning

- (1) association of the trade dress with a particular source by actual purchasers (typically measured by customer surveys);
- (2) length, degree, and exclusivity of use;
- (3) amount and manner of advertising;
- (4) amount of sales and number of customers;
- (5) intentional copying; and
- (6) unsolicited media coverage of the product embodying the mark.

Converse v. ITC

Federal Circuit

Major issue was length, degree and exclusivity of use

- 5 year standard at PTO
- 5 year period prior to date of infringement should be date of determination
- survey or evidence must relate to that period

Converse v. ITC

Federal Circuit

Nonexclusive use must be substantially similar

- Same rule as to infringement
- What about missing elements?
- Similar = confusing?



Converse v. ITC

Federal Circuit

Remand to the ITC to sort it all out

Questions?