

Welcome to Hauptman Ham, LLP's Case Law Review, a summary of recent important intellectual property decisions.

Table of Contents

Clinical Proof of Effectiveness Not Effective in a Patent Claim	1
Unfocused Case Not Successful	3
Result of a General Verdict based on Erroneous Legal Theory	5
USPTO Clarifies Subject Matter Eligibility Guidance For Examiners	7
Additional Information	9

CLINICAL PROOF OF EFFECTIVENESS NOT EFFECTIVE IN A PATENT CLAIM

[Bayer Pharma v. Mylan Pharms. Inc.](#)

Appeal No. 2023-2434 (Fed. Cir., September 23, 2025, Moore, Cunningham, Scarsi¹, precedential)

Author: [Gregory P. Brummett](#)

Key Points:

- In a patent claim for a method of treatment that relies on a known product, reciting post hoc success in clinical trials does not make the claim patentable.
- 이미 알려진 제품(known product)을 이용한 치료 방법(method of treatment)에 대한 특허청구항에서는, 임상시험(clinical trial)에서 사후적으로 입증된 성공(post hoc success)을 청구항에 기재하더라도 특허성을 인정받을 수 없다.
- 既知の製品に依拠する治療方法のクレームにおいて、臨床試験での事後成功 (post hoc success) を要件とすることは、そのクレームの特許性を認めるものではない。
- 对于依赖已知产品的治疗方法专利权利要求·援引事后 (post hoc) 临床试验取得成功·并不能使该权利要求具有可专利性。

Background:

Bayer Pharma (“Bayer”) owns U.S. Pat. No. 10,828,310 (“the ‘310 patent”), which describes the results of a Phase III clinical trial that evaluated the efficacy and safety of administering rivaroxaban (an anticoagulant sold under the XARELTO® mark) with and without aspirin for the prevention of major adverse cardiac events associated with blood clots. The claims of the ‘310 patent are directed to methods for reducing the risk of

¹ United States District Court for the Central District of California, sitting by designation.

cardiovascular events in patients with coronary artery disease (CAD) and/or peripheral artery disease (PAD) by administering a combination of rivaroxaban and aspirin. Claim 1 of the '310 patent recites:

1. A method of reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral artery disease, comprising administering to the human patient rivaroxaban and aspirin *in amounts that are clinically proven effective* in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral arterial disease, *wherein rivaroxaban is administered in an amount of 2.5 mg twice daily and aspirin is administered in an amount of 75-100 mg daily.* (emphasis added)

Mylan Pharmaceuticals Inc. ("Mylan") petitioned for *inter partes* review ("IPR") challenging the validity of the claims of the '310 patent arguing 1) that claims 1–2 are anticipated by prior art of Foley and 2) that claims 1–8 are obvious over Foley alone or Foley in combination with prior art of Plosker. The Patent Trial and Appeals Board ("Board") construed the "clinically proven effective" language as non-limiting and also found, in the alternative, that this claim language is inherently anticipated. The Board also construed "first product comprising rivaroxaban and aspirin" to encompass administration of rivaroxaban and aspirin as separate dosage forms. The Board held the challenged claims unpatentable based on Foley and Plosker.

Holding:

The Federal Circuit affirmed the Board's judgment holding claims 1-4 of the '310 patent unpatentable, vacated the judgment of unpatentability with respect to claims 5-8, and remanded.

Discussion:

On appeal, Bayer argued that the Board had failed to explain why an artisan would have combined Foley and Plosker with a reasonable expectation of success and had failed to analyze whether clinical proof of efficacy was an "unexpected result." The Federal Circuit rejected Bayer's argument, explaining that an otherwise anticipated product cannot be made patentable merely by adding a limitation that the product performed well in a clinical trial. The phrase "clinically proven effective" has no functional relationship with the claimed method, since proving the product clinically effective changes nothing about the method of administering the product.

The court rejected Bayer's argument that *Allergan Sales, LLC v. Sandoz, Inc.*, 935 F.3d 1370 (Fed. Cir. 2019) controls and requires treating "clinically proven effective" as material to patentability. The court explained that *Allergan* addressed certain "wherein" clauses that limited the claimed composition by specifying safety and efficacy benchmarks the claimed composition must meet. The court found that, in these claims, "clinically proven effective" serves no analogous function.

The court found the Board improperly construed the phrase "a first product" in claim 5, leading to an erroneous conclusion of obviousness. The Board concluded that "first product comprising rivaroxaban and aspirin" could cover administration of two different dosage forms. Giving effect to the phrase, the court determined that the plain language requires a single dosage form that includes the two drugs.

Focus Prod. Group Int'l v. Kartri Sales Co., Inc.

Appeal No. 2023-1446 (Fed. Cir., Sept. 30, 2025, Moore, Clevenger, Chen, precedential)

Author: Joshua A. Hauptman

Key Points:

- In patent prosecution, an election made in response to a species restriction can create prosecution disclaimer.
- 특허 심사 과정에서 종 제한요구(species restriction)에 따라 특정 종을 선택(election)한 경우, 그 선택이 이후 출원경과상 권리포기(prosecution disclaimer)를 발생시킬 수 있다.
- 特許出願審査中、種の選択要求の応答としての選択が、審査権利放棄となる。
- 在专利审查过程中，对物种限制作出的选择可能构成审查过程中的放弃声明（prosecution disclaimer）。
- In trademark litigation, a licensee cannot sue for infringement without the owner of the mark.
- 상표(trademark) 침해소송에서, 상표권자가 함께 소송에 참여하지 않는 한 실시권자(licensee)는 단독으로 침해소송을 제기할 수 없다.
- 商標権訴訟において、ライセンシーは、その商標権利者と共にでなければ、侵害訴訟を提起できない。
- 在商标侵权诉讼中，未经商标权人共同参与，商标被许可人（licensee）无权单独提起侵权诉讼。
- Patenting any element of trade dress creates a heavy presumption that the element is functional and not protectable as trade dress.
- 트레이드 드레스(trade dress)를 구성하는 요소 중 어느 하나라도 특허를 받은 경우, 해당 요소는 기능적(functional)이라는 강한 추정(heavy presumption)을 받게 되며, 트레이드 드레스로서 보호받기 어렵다.
- トレードドレスの要素を特許権利化することが、その要素が機能的でありトレードドレスとして保護され得ないとする重要な推定の根拠となる。
- 如果将商业外观（trade dress）的任何组成要素申请并获得专利，将产生该要素具有功能性（functional）且不受商业外观保护的强烈推定（heavy presumption）。
- An objectively reasonable defense, even if unsuccessful at trial, can negate a finding of willful infringement and shield against enhanced damages.
- 객관적으로 합리적인 방어(objectively reasonable defense)는 비록 재판에서 받아들여지지 않았더라도, 고의침해(willful infringement) 인정이 부정될 수 있으며 증액손해배상(enhanced damages)을 피하는 근거가 될 수 있다.
- 客観的に合理的な抗弁は、たとえそれが公判において成功しなくとも、故意侵害の認定を否定しかつ損害賠償額引き上げの盾となる。
- 即使被告最终在审判中败诉，只要其提出了客观上合理（objectively reasonable）的抗辩理由，仍可否定故意侵权（willful infringement）的认定，并避免承担加重赔偿（enhanced damages）。

- A co-appellant who files an incomplete brief waives any issues not included in the brief even where another co-appellant briefs those issues.
- 공동 항소인(co-appellant)이 제출한 항소이유서(brief)가 불완전한 경우, 다른 공동 항소인이 해당 쟁점을 충분히 다루었다더라도 자신의 항소이유서에 포함하지 않은 쟁점은 포기(waiver)한 것으로 본다.
- 不完全な書類を提出する共同控訴人は、その書類に含まれていないいかなる争点を、たとえ他の共同控訴人の書類にそれが含まれていたとしても、放棄する。
- 共同上诉人 (co-appellant) 提交的上诉状 (brief) 若未完整涵盖相关争议, 则其未提出的争议视为放弃 (waived), 即使另一共同上诉人在其上诉状中对这些争议进行了论述, 也不影响该放弃的效力。

Background:

Focus Products Group (“Focus”) owns U.S. Patent Nos. 6,494,248 (“’248 patent”), 7,296,609 (“’609 patent”), and 8,235,088 (“’088 patent”) directed to shower curtains that have embedded rings for hanging, rather than hooks. Focus also owns the trademarks “HOOKLESS”® and “EZ ON”®. The “EZ ON” mark was registered during this litigation. Finally, Focus asserts ownership of trade dress expressed in shower curtain products sold under the above marks and covered by the above patents. Focus claimed infringement of the patents, trademarks, and trade dress.

The district court denied defendants’ motion to change venue, and unclean hands and equitable estoppel defenses, as untimely presented, construed several terms in the asserted claims, and granted summary judgment of infringement to Focus regarding the patents. The district court tried the question of whether Focus owned the EZ ON mark at the time its complaint was filed, and found that Focus had standing to enforce the mark and granted judgment of infringement. Also at trial, the district court found that defendants infringed the HOOKLESS mark and the trade dress. The district court held the infringement willful and awarded significant damages, lost profits, and attorney's fees. Defendants appealed.

Holding:

The United States Court of Appeals for the Federal Circuit (“Federal Circuit”) affirmed denial of the venue change motion and the unclean hands motion. The Federal Circuit reversed the summary judgment of infringement regarding the ‘248 and ‘609 patents due to faulty claim construction and vacated the summary judgment of infringement regarding the ‘088 patent due to insufficient analysis, but only for one defendant, affirming the summary judgment for another defendant due to improper briefing, resulting in waiver on appeal. The Federal Circuit also vacated the judgment of infringement of the HOOKLESS mark as supported by erroneous analysis, but for only one defendant, finding waiver regarding the other defendant. Finally, the Federal Circuit reversed the judgment of infringement of the EZ ON mark for lack of standing, and vacated the trade dress infringement finding due to incomplete analysis, for all defendants.

Discussion:

The Federal Circuit found that the district court had construed the word “rings” too broadly in the claims of the ‘248 and ‘609 patents. By electing to prosecute rings with “projecting fingers” and acquiescing to the cancellation of claims for “flat upper edge” rings, Focus clearly and unmistakably disclaimed rings having flat upper edges, like the accused rings. Because the district court failed to find prosecution disclaimer, the Federal Circuit reversed summary judgment of infringement based on the faulty claim construction.

The Federal Circuit also found that the district court had not provided analysis sufficient to support summary judgment of infringement regarding the '088 patent. According to the reviewing court, the district court's analysis did not sufficiently explain how the accused flat-topped ring had a "projecting edge" as required by the claims, especially given its similarity to a patent figure that lacks one. The district court's holding was, therefore, conclusory, and was vacated and remanded.

The Federal Circuit also found that the district court had improperly found willful infringement. The reviewing court explained that, by treating a lack of formal "advice of counsel" as proof of bad faith in analyzing willfulness, and by ignoring objectively reasonable, good faith defenses, which were successful on appeal, the district court erred in awarding enhanced damages.

Regarding whether Focus had standing to sue under the EZ ON mark, the Federal Circuit found that a pre-suit licensing agreement in the record did not prove ownership of the mark, and that formal transfer of the mark to Focus occurred years after litigation commenced. Because Focus did not own the EZ ON mark when litigation began, Focus did not have standing to sue under the EZ ON mark.

The Federal Circuit also found that the district court erred in its analysis of infringement of the HOOKLESS mark. The reviewing court explained that the district court had incorrectly focused on physical similarity of the products being sold, rather than comparing the marks used by the parties as they appear in commerce. The district court did not analyze whether defendant's use of the word "hookless" in describing its product commercially amounted to trademark infringement, and a mere comparison of products cannot establish trademark infringement.

In analyzing the trade dress question, the Federal Circuit found that the district court erred by incompletely analyzing functionality of the elements of the trade dress. Although the district court found that a "neat and orderly" appearance, an asserted element of the trade dress, is not essential to any function, and that alternative designs, even involving use of hooks, can give such appearance, the district court failed to consider arguments that the trade dress elements had been patented. Finding the district court's analysis in this regard incomplete, the Federal Circuit remanded for reconsideration of functionality.

Finally, the Federal Circuit found that, by filing separate briefs arguing different issues of the appeal, each co-appellant had waived issues not raised in its individual brief resulting in different judgments for the two co-appellants.

RESULT OF A GENERAL VERDICT BASED ON ERRONEOUS LEGAL THEORY

Magēmā Tech. LLC v. Phillips 66

Appeal No. 2024-1342 (Fed. Cir., September 8, 2025, Moore, Stoll, and Bumb,² precedential)

Author: Michael P. McComas

Key Points:

- Where a jury's general verdict is based on an erroneous legal theory, the general verdict can only be upheld as harmless error if a court is "totally satisfied" or "reasonably certain" that the verdict was not based on the erroneous theory.
- 배심원의 일반 평결(general verdict)이 잘못된 법률 이론(erroneous legal theory)에 기초한 경우, 법원이 그 평결이 해당 잘못된 이론에 근거하지 않았다는 점에 대해 '완전히 확신(totally

² United States District Court for the District of New Jersey, sitting by designation.

satisfied)'하거나 '합리적으로 확신(reasonably certain)'하는 경우에만 그 오류를 무해한 오류(harmless error)로 보아 그 평결을 유지할 수 있다.

- 陪審の一般評決が誤った法理論に基づいている場合、裁判所がその評決が誤った理論に基づいていなかったものとして“全体として満足”あるいは“合理的信頼”している場合は、その一般評決を、無害な誤りとして支持する。
- 当陪審团作出的一般裁决 (general verdict) 基于错误的法律理论时, 只有法院“完全确信 (totally satisfied) ”或“有合理确定性 (reasonably certain) ”该裁决并非基于该错误理论作出时, 才能将该错误认定为无害错误 (harmless error), 从而维持该裁决。

Background:

In 2016, the International Maritime Organization lowered its sulfur specification on heavy marine fuel oil (HMFO) from 3.5 % (by weight) to 0.5 %. Magēmā Technology, Inc. (“Magēmā”) developed a patent family, including US Patent No. 10,308,884 (“the ‘884 patent”), directed to desulfurizing high-sulfur HMFO that is otherwise compliant with the relevant ISO standard to produce low-sulfur HMFO. After Magēmā discussed licensing the technology with Phillips 66 and co-defendants (“Phillips”), no agreement was reached. Phillips announced plans to formulate low-sulfur HMFO, and Magēmā sued Phillips for infringement of multiple patent claims including claims 1 and 5 of the ‘884 patent.

At trial in the U. S. District Court for the Southern District of Texas (“the district court”), a jury returned a general verdict of no infringement of the two ‘884 patent claims. Magēmā unsuccessfully moved for a new trial based on Phillips’ arguments that actual test data were needed to prove infringement, despite arguing to the contrary to avoid producing such data during discovery. The district court agreed that the arguments were “improper and prejudicial” but held them to be harmless error that did not affect the outcome of the trial.

Holding:

The U. S. Court of Appeals for the Federal Circuit (“the Federal Circuit”), uneasy about the contrary positions Phillips took during trial, reversed and remanded for a new trial.

Discussion:

Claims 1 and 5 of the ‘884 patent recite that “prior to hydroprocessing the high sulfur heavy marine fuel oil is compliant with ISO 8217:2017,” which defines a minimum HMFO flashpoint of 140°F. During discovery, Phillips argued that producing actual flashpoint data by testing “inside the battery limits” as requested by Magēmā would be too dangerous, and that a “Riazi Formula” estimate could be used to prove compliance with the flashpoint standard. At trial, Phillips instead argued that actual testing data would be needed, even after being instructed by the district court not to do so. In concluding that Phillips’ mutually exclusive arguments amounted to harmless error, the district court indicated that the jury could have based its noninfringement verdict on claim limitations other than being “compliant with ISO 8217:2017.”

The Federal Circuit explained, however, that because a general verdict indicates only “yes” or “no” as to infringement of each claim at issue, there was no way to know which limitations the jury relied on for its decisions. Without such information, according to the Federal Circuit, the high degree of certainty that the district court should have needed to reach its conclusion was not present. In reversing the district court, the Federal Circuit stated that “[w]e may only uphold a jury’s general verdict with an erroneously submitted theory under a ‘harmless error gloss’ if we are ‘totally satisfied’ or ‘reasonably certain’ that the verdict was not based

on the erroneously submitted theory.” *Muth*, 461 F.3d at 564–65 (quoting *Baun v. Flynt*, 731 F.2d 1205, 1206 (5th Cir. 1984)).”

USPTO CLARIFIES SUBJECT MATTER ELIGIBILITY GUIDANCE FOR EXAMINERS

USPTO Memorandum issued to Examiners on August 4, 2025, entitled “Reminders on evaluating subject matter eligibility of claims under 35 U.S.C. 101”

Author: Dongjin Park

Key Points:

- Claim elements that cannot be performed by the human mind do not fall into the abstract category of mental processes.
- 사람의 정신적 사고(human mind)만으로는 수행될 수 없는 청구항 요소는 추상적 아이디어(abstract idea)로서 '정신적 과정(mental processes)'에 해당하지 않는다.
- 人間の心の中で実行し得ないクレーム要件は、メンタルプロセスとしての抽象的概念のカテゴリに含まれない。
- 无法由人类思维完成的权利要求要素，不属于抽象概念中的“心理过程（mental processes）”类别。
- To be rejected as ineligible at Step 2A for reciting a mathematical relation, a claim must expressly recite a mathematical calculation or algorithm.
- 수학적 관계(mathematical relation)를 기재했다는 이유로 Step 2A에서 특허적격성(ineligibility)을 이유로 거절되기 위해서는, 청구항이 수학적 계산(mathematical calculation) 또는 알고리즘(algorithm)을 명시적으로(expressly) 기재해야 한다.
- 数学的關係性に関してStep 2Aにおける特許適格性否定を理由として拒絶されるためには、クレームが明確に数学的計算式あるいはアルゴリズムを要件としていなければならない。
- 要在美国专利适格性分析第2A步（Step 2A）中以“记载数学关系（mathematical relation）”为由驳回权利要求，权利要求必须明确记载数学计算（mathematical calculation）或算法（algorithm）。
- A claim that does not expressly recite a technological improvement may be patent eligible if the improvement achieved by the invention is apparent to a person skilled in the art from the description in the specification.
- 청구항이 기술적 개선을 명시적으로 기재하지 않았더라도, 명세서의 기재를 통해 당업자가 해당 발명의 기술적 개선을 이해할 수 있다면 특허적격성(patent eligibility)이 인정될 수 있다.
- 技術的向上を明確に要件としていないクレームは、もしその発明により達成されるその向上が明細書の記載から当業者に明らかであるのであれば、特許適格性を有する。

- 即使权利要求未明确记载技术改进 (technological improvement)，如果本领域技术人员能够根据说明书 (specification) 的描述认识到该发明实现了技术改进，则该权利要求仍可能符合专利适格性 (patent eligibility)。

The United States Patent and Trademark Office issued this memorandum to supplement guidance to Examiners in examining the subject matter eligibility of patent claims under 35 U.S.C. § 101. The memorandum has the potential to affect the patentability of software, artificial intelligence, and machine learning inventions, where patentability often turns on whether the claims are directed to judicial exceptions to the broad categories of patentable inventions set forth in section 101, like abstract ideas or mathematical relations.

The memorandum highlights four key issues that examiners frequently encounter in eligibility analysis:

1. Reliance on the mental process category of abstract ideas
2. Distinguishing claims that *recite* a judicial exception from those that merely *involve* one
3. Analyzing the claim as a whole
4. Considering whether a claim represents a technological improvement, or simply uses a computer as a tool to apply an abstract idea

Especially in the context of AI-related claims, the memorandum reminds Examiners that, before analyzing subject matter eligibility, Examiners must first establish the broadest reasonable interpretation of the claim, and that they should only reject a claim when it's *more likely than not* that the claim is ineligible, not if it's a close call. Unpatentability for any reason must be established by preponderance of the evidence, and Examiners must, in all cases, conduct a complete examination of every claim under all patentability requirements.

Regarding considerations of mental processes under Step 2A of Prong One, a claim is said to recite a mental process when it includes steps that can practically be performed in the human mind, such as observations, evaluations, or judgments, or by a human using a pen and paper. Claim elements that cannot be performed by the human mind, such as complex AI model training or hardware-based computations, do not fall under this category. Examiners are cautioned not to overextend the mental process analogy to cover operations that are beyond human capability.

The memorandum addresses the distinction between claims that recite judicial exceptions and those that do not by pointing to existing examples in the USPTO subject matter eligibility literature. Pointing to Example 39, the claim in that example reciting “*training the neural network in a first stage using the first training set*” does not recite mathematical relationships or formulas. Although the claim involves an abstract idea, it does not recite an abstract idea and is patent eligible. In contrast, the claim in Example 47 recites “*training, by the computer, the ANN based on the input data and a selected training algorithm ... wherein the selected training algorithm includes a backpropagation algorithm and a gradient descent algorithm.*” Since this language expressly refers to specific mathematical calculations, it actually recites an abstract idea. So, including a concept like “training a neural network” that merely involves an abstract idea does not make a claim ineligible, but naming a particular mathematical algorithm recites an abstract idea.

In Step 2A, Prong Two, the question here is whether, for a claim found abstract in Prong One, additional elements in the claim integrate the judicial exception into a practical application. Examiners must evaluate how all claim limitations interact with each other, rather than isolating them. Even if a claim uses a generic computer, it can still be eligible if the additional limitations meaningfully limit the abstract idea or transform it into a practical technological application.

In Step 2B, Examiners may conclude that a claim is eligible if it reflects an improvement in computer functionality or in another technical field. This is sometimes described as the “search for a technological solution to a technological problem.” The key question here is whether the claim describes a specific way to solve a problem, rather than merely claiming the idea of a solution. Examiners are reminded to consult the specification to determine whether the disclosed invention truly improves technology or a technical field. The improvement does not have to be expressly stated, as long as it’s apparent to a person skilled in the art from the description.

In a related matter, often overlapping with the improvements analysis above, Examiners are cautioned not to expand the scope of the “apply it” inquiry. While a claim that merely recites “apply the abstract idea using a computer,” or a claim that merely automates a manual business process, is not patent eligible, Examiners must avoid oversimplifying claims to resemble such categories. Examiners should instead ask:

1. Does the claim describe a specific technical solution, or just the idea of one?
2. Does it use a computer as a simple tool, or does it improve the computer’s functionality?
3. How specific or general is the claimed application?

Thus, while automating a manual business process isn’t enough, improving network intrusion detection or data analysis accuracy would be considered a technological improvement.

Patent practitioners should avoid reciting, in patent claims, elements that can be performed in the human mind or elements that recite judicial exceptions such as mathematical relations. Where a claim likely recites a judicial exception, add language that incorporates the judicial exception into a practical application. Rather than merely reciting an idea of a solution to a technical problem (broad), recite the actual solution (narrow). Also, be sure to describe technological improvements in the specification to relate to the technical solutions recited in the claims.

ADDITIONAL INFORMATION

2318 Mill Road, Suite 1400
Alexandria, VA 22314 USA

Tel: +1 (703) 684-1111
Fax: +1 (703) 518-5499

Chiyoda Kaikan Bldg. 6F
1-6-17 Kudan Minami, Chiyoda-Ku,
Tokyo 102-0074 Japan

Tel: +81 3 6256-8970
Fax: +81 3 6717-2845

Room B565, No. 5 building
Huayangnian Meinian International Square
Nanshan District, Shenzhen, China, 518067

H-Business Park D 314, 26
Beobwon-ro 9-gil, Songpa-gu
Seoul, Korea

Tel: +82 (0)2 6412-0626
Fax : +82 (0)2 6412-0627

The articles in this newsletter are for informational purposes only and not for the purpose of providing legal advice or soliciting legal business. You should contact your attorney to obtain advice about each issue. Use of and access to this newsletter or any of the e-mail links contained herein do not create an attorney-client relationship between Hauptman Ham, LLP and the user. The opinions expressed at or through this newsletter are the opinions of the individual author and may not reflect the opinions of the firm, any individual attorney, or the firm's clients. Unsolicited information sent to Hauptman Ham, LLP by persons who are not clients of the firm is not subject to any duty of confidentiality on the part of Hauptman Ham, LLP.

All rights reserved. ©2025