

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

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SUBSEQUENT PROSECUTION HISTORY DOES NOT DISCLAIM

Azurity Pharms., Inc. v. Alkem Labs., Ltd.

Appeal No. 2023-1977 (Fed. Cir., April 8, 2025, Moore, Chen, and Murphy¹, precedential)

Author: Michael McComas

Key Points:

- A disclaimer made during prosecution of a first patent applies equally to a child application of the first patent, and its scope is not limited by a statement submitted during prosecution of a second child application after allowance of the claims in the child application.
- 第1の特許の審査中になされた免責（ディスクレーマ）は、その第1の特許の子出願にも等しく適用され、その範囲は、子出願のクレームが認可された後の第2の子出願の審査中に提出された陳述内容に限定されない。
- 원출원 특허의 심사과정에서 이루어진 Disclaimer는 해당 특허의 계속출원에도 동일하게 적용되며, 계속출원의 청구항이 허용된 이후 두 번째 계속출원의 심사 과정에서 제출된 진술(Statement)에 의해 그 범위가 제한되지 않는다.
- 在第一项专利审查过程中作出的免责声明，同样适用于该第一项专利的子申请，其适用范围不会因在另一子申请的审查过程中于该子申请权利要求获准后提交的陈述而受到限制。

Background:

After Alkem Laboratories, Ltd. (“Alkem”) submitted an Abbreviated New Drug Application (ANDA) for a product including propylene glycol, Azurity Pharmaceuticals, Inc. (“Azurity”), owner of a patent family including U. S. Patent No. 10,959,948 (“the ‘948 patent”) directed to drinkable liquid formulations including

¹ E.D. Pa. Sitting by designation.

vancomycin, an antibiotic used to treat *Clostridium difficile* (C. diff), sued Alkem for infringement of claims 5, 7, 8, and 9 of the '948 patent.

The U. S. District Court for the District of Delaware (“the district court”) found no infringement of the '948 patent claims because Azurity had disclaimed any presence of propylene glycol during prosecution, finding Azurity’s interpretation of a stipulation, ambiguously stating that suitable flavoring agents “for use in the Asserted Claims include flavoring agents with or without propylene glycol” and entered during discovery, “unpersuasive.”

Holding:

The U. S. Court of Appeals for the Federal Circuit (“the Federal Circuit”) agreed with the district court, holding that a statement by Azurity submitted in a co-pending application from the same family, after allowance of the claims of the '948 patent, to have no weight in construing the claims allowed prior to the statement.

Discussion:

During prosecution of the parent application of the '948 patent, Azurity added “consisting of” or “consists of” language to multiple claims to distinguish over applied prior art references in which liquid formulations include propylene glycol and declared that “the diluent and the compounded solutions do not have propylene glycol or polyethylene glycol.” The Federal Circuit, agreeing with the district court, stated that, based on the prosecution history of the '948 patent and its parent, “Azurity’s disclaimer of propylene glycol in the claims of the '948 patent was clear, unambiguous, and complete.” The Federal Circuit also found that Azurity’s attempted withdrawal of the disclaimer was submitted in another application in the same family after allowance of the claims of the '948 patent, and thus have no weight in construction of those claims.

The Federal Circuit also rejected Azurity’s argument that the stipulation, “[s]uitable flavoring agents for use in the Asserted Claims include flavoring agents with or without propylene glycol,” overcame the disclaimer of propylene glycol. The reviewing court explained that the disputed stipulation, coming at the end of a long list of stipulations, did not reference the language of any claim and was thus inconsistent with other stipulations in the list that mentioned specific claims. The reviewing court also found that during litigation of the stipulations, Azurity admitted “that the plain and ordinary meaning of the claim term ‘flavoring agent’ includes flavoring agents without propylene glycol,” so the stipulation could not be applied to overcome the disclaimer.

‘PAYMENT HANDLER’ IS A MEANS-PLUS-FUNCTION CLAIM TERM

Fintiv, Inc. V. PayPal Holdings, Inc.

Appeal No. 2023-2312 (Fed. Cir., April 30, 2025, Prost, Taranto and Stark, precedential)

Author: Bobbie Wu

Key Points:

- In a patent claim, the term “payment handler” is a functional term that, without further terms reciting structure or algorithm, makes the claim a means-plus-function claim under 35 U.S.C. § 112(f).
- The term “payment handler” is a functional term that, without further terms reciting structure or algorithm, makes the claim a means-plus-function claim under 35 U.S.C. § 112(f).

- [illegible]

CANCELATION OF A GENERIC COLOR MARK

In re PT Medisafe Techs.

Appeal No. 2023-1573 (Fed. Cir., April 29, 2025, Prose, Clevenger, and Stark, precedential)

Author: Gregory P. Brummett

Key Points:

- Overturning a holding by the Trademark Trial and Appeals Board that a color mark is generic requires submitting evidence showing that the color can identify a source in the mind of the relevant public for the goods sought to be protected.
- 商標審判部 (Trademark Trial and Appeals Board)によるカラー商標が一般的なものであるとする判断を覆すには、その保護されるべき物品のカラーを、関連する公衆の意識内で出所を特定することができることを示す証拠を提出する必要がある。
- 상표심판원(Trademark Trial and Appeals Board)이 색채 표지가 보통명칭적이라는 판단을 뒤집기 위해서는, 관련 대중이 해당 색채로 보호 대상 상품의 출처를 식별할 수 있다는 점을 입증하는 증거를 제출해야 한다.
- 要推翻商标审判与上诉委员会 (TTAB) 关于颜色标志属通用标志的裁定，需要提交证据证明该颜色能够在相关公众心中对拟受保护商品起到识别来源的作用。

Background:

PT Medisafe Technologies (“Medisafe”), a medical glove manufacturer and distributor, applied to the United States Patent and Trademark Office (“USPTO”) for registration of a color mark, the color “dark green (Pantone 3285c),” for chloroprene examination gloves. The USPTO found the proposed mark lacked distinctiveness and refused registration without a showing of acquired distinctiveness. Medisafe attempted such showing, without success, the USPTO finding the proposed mark generic. In applying a test established in *Milwaukee Electric Tool Corp. v. Freud America, Inc.*, 2019 WL 6522400 (T.T.A.B. Dec. 2, 2019), the Trademark Trial and Appeals Board (“TTAB”) rejected Medisafe’s argument that the proper genus for consideration is gloves sold to authorized resellers and defined the applicable genus as all “chloroprene examination gloves.” The TTAB then affirmed the Examiner, finding that the relevant public everyone who might purchase such gloves. Medisafe appealed.

Holding:

The Examining Attorney and the TTAB had correctly applied the *Milwaukee* test in finding that the color of the Medisafe was generic and was not entitled to registration on the primary or secondary registers. Affirmed.

Discussion:

The *Milwaukee* test is a modification of the test in *H. Marvin Ginn Corp. v. International Ass’n of Fire Chiefs, Inc.*, 782 F.2d 987, 990 (Fed. Cir. 1986), which in determining genericness asks, First, what is the genus of goods or services at issue? Second, is the term sought to be registered or retained on the register understood by the relevant public primarily to refer to that genus of goods or services?

Milwaukee slightly modifies the second question to tailor the test to color marks, asking whether the color is understood as a category or type of trade dress for the goods or services.

The Federal Circuit first rejected Medisafe's argument that the statutory language allows a mark to be canceled only where that mark is a "generic name." The court noted that its prior case of *Sunrise Jewelry Mfg. Corp. v. Fred S.A.*, 175 F.3d 1322 (Fed. Cir. 1999), held that the statutory language also applies to trade dress, including a color mark.

Applying the above test, the Federal Circuit then affirmed the TTAB. Finding no error in the TTAB's determination that the proper genus is all chloroprene medical examination gloves, based at least on Medisafe's identification of the goods in its application for trademark as "[m]edical examination gloves," the Federal Circuit found no reason in the record to limit the genus only to "authorized resellers." The Federal Circuit then considered the TTAB's treatment of the evidence of gloves in the industry and agreed that the color sought by Medisafe is so common in chloroprene gloves that it "cannot identify a single source."

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

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