

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

Table of Contents

Written Description Support for Jepson Preamble	1
Start Date for Patent Term Extension of Reissued Patents	3
Section 337 Protection for Patented Goods Manufactured Abroad	4
Applicability of Zone of Natural Extension Doctrine in Trademark Cases	6
Additional Information	7

WRITTEN DESCRIPTION SUPPORT FOR JEPSON PREAMBLE

In re: Xencor, Inc.

Appeal No. 2024-1870 (Fed. Cir., March 13, 2025, Hughes, Stark, Schroeder¹)

Author: Jay P. Beale

Key Points:

- The preamble of a Jepson claim must be supported by adequate written description.
- ジェプソン型クレームのプリアンブル（前段）部が明細書中で適切にサポート（記載）されていなければならない。
- Jepson 청구항의 서문(preamble)은 명세서에서 충분히 설명되어야 한다.
- Jepson 式权利要求的前言部分必须有充分的书面说明支持。
- Written description support for the preamble of a Jepson claim must establish that what is claimed to be well-known in the prior art is, in fact, well-known in the prior art.
- ジェプソン型クレームのプリアンブル（前段）部に対する明細書中のサポート（記載）が、先行技術において公知とされるべき何がクレームされているかを確立していなければならない。実際のところ、その先行技術の中で何が公知か、である。
- 선행 기술에서 잘 알려진 사항이라고 Jepson 청구항 서문에서 주장한다면 실제로 선행 기술에서 알려져 있다는 것이 명세서에 설명되어 있어야 한다.
- Jepson 式权利要求前言部分的书面说明支持必须证明，其所称为现有技术中公知的内容，确实在现有技术中是公知的。

Background:

Claims in Xencor's application for patent were rejected by the United States Patent and Trademark Office ("USPTO") during appeals that involved the Examiner, the Patent Trial and Appeal Board ("PTAB") and, ultimately, the newly-formed Appeals Review Panel ("ARP"). The USPTO determined that the preamble of Xencor's independent method claims, one of which is a Jepson claim (a patent claim in which a preamble recites conventional elements and the body of the claim recites an "improvement"), contained limiting elements that were not supported by adequate written description in the specification as required by 35 U.S.C. § 112(a). Following the ARP decision affirming the PTAB result, Xencor appealed to the Court of Appeals for the Federal Circuit.

Holding:

The Federal Circuit affirmed the USPTO, holding that limiting terms in the preamble of a Jepson claim must be supported by sufficient written description support. The Federal Circuit agreed with the ARP that the preambles of the challenged claims were limiting, and that limiting elements of the preamble were not adequately supported, and were thus unpatentable.

Discussion:

Xencor's rejected patent application presented independent claims 8 and 9, of which claim 8 was in Jepson format. The preamble of each claim recited "treating a patient," which is the phrase in controversy for this case. The USPTO found the phrase limiting in both claims, and further found that the specification lacked description of treating patients using anti-C5 antibodies recited in the preamble of both claims. The Office stated that the specification does not describe what patients, with what diseases or conditions, can be treated successfully using such antibodies. Nor does the specification contain any working examples of such treatments. Thus, the USPTO found both claims lacking written description support for the preamble phrase "treating a patient."

The Federal Circuit rejected Xencor's arguments that "treating a patient" is not limiting in the preamble, that the preamble of Jepson claims require no written description support, and that in the alternative the preambles of the two claims were adequately supported by written description in the specification. Regarding claim 9, the non-Jepson claim, the court explained that some or all elements of the preamble of a patent claim can be limiting when other parts of the claim rely on predicates in the preamble, or when the preamble is otherwise necessary to give life, meaning, and vitality to the claim language. Mere statements of purpose or intended result in a preamble, however, are generally not read as limiting.

Noting that Xencor agreed that the phrase "administering an anti-C5 antibody" was limiting in claim 9, the court found "treating a patient" was necessary to give meaning to the "administering" activity, especially since the claim contained no other details of the "administering" activity, so the "administering" must depend on characteristics of the patient being treated, and since "administering" was recited as the method of "treating a patient" using the connecting word "by."

Regarding claim 8, the Jepson claim, the Federal Circuit held that the preamble of a Jepson claim, although reciting what are thought to be conventional elements, nonetheless requires written description support. The court explained that the preamble of a Jepson claim defines its scope. The Jepson claim recites an "improvement" to conventional elements. Thus, to describe such an invention adequately the specification must describe the improvement to the conventional elements, necessarily including description of the conventional elements. To require otherwise, explained the court, would violate the requirement that the written description must "allow persons of ordinary skill to recognize the [the inventor] invented what is claimed" (quoting *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010)).

Having found that the specification lacks written description support for the phrase “treating a patient,” the Federal Circuit agreed with the USPTO that claims 8 and 9 are unpatentable for lack of sufficient written description in the specification.

¹ E.D. Texas, sitting by designation.

START DATE FOR PATENT TERM EXTENSION OF REISSUED PATENTS

Merck Sharp & Dohme B.V. v. Aurobindo Pharma USA, Inc.

Appeal No. 2023-2254 (Fed. Cir., March 13, 2025, Dyk, Mayer, and Reyna, precedential)

Author: *Kien T. Le*

Key Points:

- For a reissued patent, the Hatch-Waxman patent term extension under 35 U.S.C.156(c) is calculated from the issue date of the original patent.
- 再発行特許に関し、Hatch-Waxman 特許の特許法第 156 条（c）項下の権利期間延長は、原特許（オリジナルパテント）の発行日から計算される。
- 재발행 특허(reissued patent)의 경우, 35 U.S.C. § 156(c)에 따른 Hatch-Waxman 특허 기간 연장은 원 특허의 등록(issue)일을 기준으로 계산된다.
- 对于再颁专利，根据 35 U.S.C. §156(c) 的 Hatch-Waxman 专利期限延长期限，应自原始专利的授权日开始计算。

Background:

This case concerns patent term extensions (“PTE”) for reissued patents under the Hatch-Waxman Act codified in 35 U.S.C.156 (“section 156”). The Hatch-Waxman Act provides a process for extending patent terms by up to five years to compensate patent owners for time lost during the lengthy regulatory review of new drug applications. The formula for calculating PTE is set forth in 35 U.S.C. § 156(c) (“subsection 156(c)”), which provides that “[t]he term of a patent... shall be extended by the time equal to the regulatory review period... occur[ring] after the date the patent is issued.” The question in this case is whether PTE for a reissued patent should be calculated based on the issue date of the original patent or the reissued patent; in other words, whether the reference to “the patent” in subsection 156(c) is to the original patent or the reissued patent.

Holding:

Aurobindo, the defendant, argued based on the plain meaning of subsection 156(c) that “the patent” refers to the reissued patent, and therefore the Patent Owner is entitled to shorter PTE. Merck, the Patent Owner, argued that the text of subsection 156(c), together with other patent statutes, demonstrates that subsection 156(c) refers to the original patent, and therefore the Patent Owner is entitled, in this case, to the full 5-year PTE. The USPTO, District Court and the U.S. Court of Appeals for the Federal Circuit (“CAFC”) agreed with Merck.

CAFC relied on the decision by the Supreme Court of the United States in *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 412 (2012), which considered statutory text and context together, when the meaning of the statutory text was ambiguous. Applying *Caraco*, CAFC interpreted the term “the patent” with

reference to the specific context in which that language is used in the statute, and the broader context of the statute as a whole. CAFC found that the purpose of section 156 is to compensate pharmaceutical companies for the effective truncation of their patent terms while waiting for regulatory approval of new drug applications, and that construing “the patent” in subsection 156(c) as the original patent compensates Merck for the period of exclusivity lost due to regulatory delay. CAFC held that a reissued patent is entitled to PTE based on the original patent’s issue date where, as in this case, the original patent included the same claims directed to a drug product subject to FDA review.

CAFC noted that difficult questions arise in cases where the original patent did not include any claims directed to the drug product and was later reissued to include broader claims directed to such products. Those questions are not addressed by CAFC in this case.

SECTION 337 PROTECTION FOR PATENTED GOODS MANUFACTURED ABROAD

Lashify, Inc. v. Int’l Trade Comm’n

Appeal No. 337-TA-1226 (Fed. Cir., February 10, 2025, Prost, Reyna, and Taranto)

Author: *Subaru Ryan Kanesaka*

Key Points:

- U.S. companies that manufacture, in other countries, products protected by U.S. patents for sale in the U.S. may seek relief under section 337 of the Tariff Act of 1930.
- 米国特許によって保護された製品を、米国において販売するために他の国において製造する米国企業は、1930年の関税法第337条下の救済を希求することができる。
- 미국 회사가 미국 특허로 보호받는 제품을 해외에서 제조하여 미국 내에서 판매하는 경우, 1930년 관세법 제337조에 따라 구제 조치를 청구할 수 있다.
- 美国公司在其他国家制造受美国专利保护并在美国销售的产品时，可以依据1930年《关税法》第337条寻求救济。
- Where a section 337 plaintiff manufactures products outside the U.S., expenses related to sales, marketing, warehousing, quality control, and/or distribution activities for those products in the U.S. cannot be excluded for purposes of paragraph (3), clause (B) of section 337 of the Tariff Act of 1930.
- 第337条の原告が米国域外で製品を製造し、その製品のために米国において販売、マーケティング、倉庫保管、品質管理、および／あるいは流通活動に関する対価を支払った場合、その原告は1930年の関税法第337条第(3)パラグラフ(B)項の目的からして除外することができない。
- 제337조 청구인이 미국 외에서 제품을 제조하는 경우에도, 해당 제품과 관련하여 미국 내에서 발생하는 판매, 마케팅, 창고관리, 품질관리 및/또는 유통 활동과 관련된 비용은 1930년 관세법(Tariff Act of 1930) 제337조 3항 B호의 적용 목적상 제외될 수 없다.
- 当第337条的原告在美国境外生产产品时，与该等产品在美的销售、营销、仓储、质量控制和/或分销活动相关的费用，在适用1930年《关税法》第337条第(3)款(B)项时不得被排除。

Background:

Lashify, Inc., an American company, distributes, markets, and sells in the United States eyelash extensions, which are manufactured abroad. Lashify, having patents covering the products, filed a complaint before the International Trade Commission (“ITC”) alleging that certain other importers of like products were violating section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, because their products infringe claims of three Lashify patents: (1) a utility patent, U.S. Patent No. 10,721,984 (“’984”); and (2) two design patents, U.S. Design Patent Nos. D877,416 (“D’416”) and D867,664 (“D’664”).

ITC determined that Lashify did not establish that a domestic industry exists in the U.S., as required in paragraph 2, and defined in paragraph 3, of section 337 to receive relief, so Lashify fails to meet the economic prong of paragraph 2 of the statute. ITC also determined that the products from Lashify meet the technical prong of section 2 of the statute because the products in question relate to the articles protected by D’416 and D’664 patents, but not to the articles protected by the ‘984 patent. Lashify appealed.

Holding:

The Court of Appeals for the Federal Circuit remanded for reconsideration of the domestic-industry requirement of the economic prong of section 337, paragraphs 2 and 3, and affirmed ITC’s finding that Lashify failed to satisfy the technical prong with respect to the ‘984 patent.

Discussion:

Section 337 provides relief against importation, but “only if an industry in the United States, relating to the articles protected by the patent . . . exists or is in the process of being established.” 19 U.S.C. § 1337(a)(2). Section 337(a)(3) states, “. . .an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent . . . concerned—... (B) significant employment of labor or capital.”

ITC determined that Lashify had not satisfied the domestic-industry requirement of the section 337. ITC excluded expenses relating to sales, marketing, warehousing, quality control, and distribution because these expenses were “no more than what a normal importer would perform upon receipt.” In vacating the ITC’s determination, the Federal Circuit concluded that clause (B) of paragraph 3 does not exclude or discount the sufficiency of significant-in-amount labor or capital that is devoted to the particular enterprise functions the Commission deemed excludable. The Federal Circuit remanded the case to the ITC to reconsider clause (B), including Lashify’s expenses for labor and capital related to sales, marketing, warehousing, quality control, and/or distribution activities, and to determine whether those qualifying expenses are significant or substantial based on “a holistic review of all relevant considerations.”

Regarding the technical prong, as applied to the ‘984 patent, that patent relates to lash extensions (or “lash fusions”) consisting of clusters of artificial hairs arrayed along a base that can be applied under the user’s natural lashes. The claims include a specific requirement that artificial hairs be “heat fused” or have a “heat fused connection.” ITC adopted a claim construction incorporating aspects of proposals from Lashify and respondent importers, concluding that “heat fused” means “joined by applying heat to form a single entity” with no boundaries or separations. Lashify uses two overseas manufacturers to produce its lashes: Manufacturer 1 using ultrasonic welding on the glue to bind fibers, and Manufacturer 2 using a different heating process wherein a base is used to hold the fibers to each other. The ITC determined that neither manufacturer’s products met the “single entity” element, thus finding that Lashify’s products are not covered by the ‘984 patent. The Federal Circuit affirmed ITC’s determination that Lashify had not established the technical prong of section 337, paragraph 2, with respect to the ‘984 patent.

APPLICABILITY OF “ZONE OF NATURAL EXTENSION DOCTRINE” IN TRADEMARK CASES

Dollar Fin. Grp., Inc. v. Brittex Fin., Inc.

Appeal No. 2023-1375 (Fed. Cir., March 19, 2025, Prost, Taranto, and Hughes, precedential)

Author: *Reina Kakimoto*

Key Points:

- The zone of natural expansion doctrine, allowing expansion of trademark coverage to related goods and services, cannot be used offensively to claim priority over another party’s earlier use of a trademark.
- 関連商品およびサービスに対する商標の保護範囲を拡張する域外適用規定 (natural expansion doctrine)の地域を、他の当事者による商標の以前の使用よりも優先すると主張するために攻撃的に用いることができない。
- 상표의 자연 확장 영역 원칙은 관련 상품 및 서비스로 상표 적용 범위를 확대할 수 있도록 허용하지만, 타인의 이전 사용(prior use)에 대한 우선권을 주장하기 위해 공격적으로 활용할 수는 없다.
- 自然扩张领域原则允许将商标保护范围扩展至相关商品和服务，但不能被用作进攻性手段以主张优先于他人对商标的在先使用。

Background:

Dollar Financial Group (DFG) has used the “MONEY MART” mark since 1984 for financial services like loan financing and check cashing. In 2013, DFG registered two new trademarks (word and design marks) including pawn brokerage and pawn shop services, claiming use since 2012. Meanwhile, Brittex Financial (or its predecessor) had been operating pawn shops in Texas under the unregistered marks “MONEY MART PAWN” and “MONEY MART PAWN & JEWELRY” since 1993. Brittex filed a petition with the Trademark Trial and Appeals Board (“the Board”) of the United States Patent and Trademark Office seeking cancellation of DFG’s registrations, citing prior common law rights and a likelihood of confusion under § 2(d) of the Lanham Act. The Board initially denied the petition, concluding that Brittex had failed to establish priority to the “MONEY MART” mark because DFG had used the mark in connection with loan financing, encompassing also pawn services, since the 1980’s whereas Brittex had not provided pawn services until 1993. The Court of Appeals for the Federal Circuit (“CAFC”) reversed the Board’s denial and remanded for further proceedings, concluding that the Board erred in holding that loan financing encompasses pawn services.

On remand, the Board held that Brittex had established priority to the “MONEY MART” mark because Brittex was the first to offer pawn services under the mark, whereas DFG had only used the mark in connection with pawn brokerage and pawn services since 2012. The Board rejected DFG’s argument that the zone of natural expansion doctrine applies to extend DFG’s priority claim, finding that doctrine to be “purely defensive.” Finding likelihood of confusion, the Board partially granted the cancellation petition. DFG appealed the ultimate partial cancellation.

Holding:

The Court of Appeals for the Federal Circuit affirmed the Board's conclusion that Britt看 established priority. The court also held that the zone of natural expansion doctrine cannot be used offensively to support a cancellation petition, and that the Board's finding of likelihood of confusion was supported by substantial evidence. The court accordingly affirmed partial cancellation of DFG's registrations by the Board.

Discussion:

Regarding priority and the zone of natural expansion doctrine, the Board found Britt看 was the first to use the "MONEY MART" mark in pawn services (1993), while DFG began use in 2012. The court rejected DFG's argument that the zone of natural expansion doctrine should be applied because pawn services are a natural extension of the loan financing business, holding that the doctrine is purely defensive. The court explained that a party may use the zone of natural extension doctrine to block others from registering conflicting marks, but not to expand its own rights retroactively. The court also rejected DFG's argument that the tacking doctrine should apply as untimely raised for the first time on appeal and therefore waived.

Regarding the likelihood of confusion, the court reviewed the *DuPont* factors (*In re E.I. DuPont DeNemours & Co.*, 476 F.2d 1357 (C.C.P.A. 1973)) and found that the Board's analysis was supported by substantial evidence:

- Regarding similarity of marks, the court found that both parties used "MONEY MART," and Britt看's additions of "PAWN" or "PAWN & JEWELRY" did not materially change the commercial impression.
- Regarding strength of the mark, the court found that "MONEY MART" was suggestive (not descriptive), giving it above-average inherent strength, although Britt看's commercial strength was found to be moderate.
- Regarding overlap in services, the court found that both parties offered pawn services, targeting similar customers in similar trade channels.
- The court found that other factors (right to exclude, market variety, bad faith) were neutral or non-dispositive.

The court accordingly held that a strong likelihood of confusion existed between the marks for pawn services.

ADDITIONAL INFORMATION

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