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Korean PTE Practice and Recent Case Law 韩国专利期限延长 (PTE) 制度 实务及最新判例

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I. Overview of the Korean PTE System

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1. Evolution of the Korean PTE System 专利期限延长 (PTE) 制度的沿革

- Korea introduced the **Patent Term Extension (PTE)** system on **July 1, 1987**, along with patent protection for chemical and pharmaceutical substances.
- 韩国**专利期限延长 (PTE)** 制度随着化学及医药物质专利保护制度的引入, 于**1987年7月1日**正式施行。
- Korea was one of the earliest jurisdictions to adopt a PTE system, following the United States.
- 韩国是继美国之后较早引入专利期限延长 (PTE) 制度的国家之一。
- The PTE system has evolved through a series of legislative amendments, with the most recent amendment taking effect on **July 22, 2025**.
- 韩国专利期限延长 (PTE) 制度历经多次修订, 最近一次的修订于**2025年7月22日**生效。
- Note: Since March 15, 2012, Korea has operated a **Patent Term Adjustment (PTA)** system to compensate patentees for patent term loss resulting from delays in patent examination.
- 注: 韩国自**2012年3月15日**起实施**专利期限调整 (Patent Term Adjustment, PTA)** 制度, 以补偿因专利审查延误而导致的专利期限损失。

2. PTE Eligibility Requirements (1) 韩国专利期限延长 (PTE) 适用要件 (1)

• Regulatory Requirements 行政审批要件

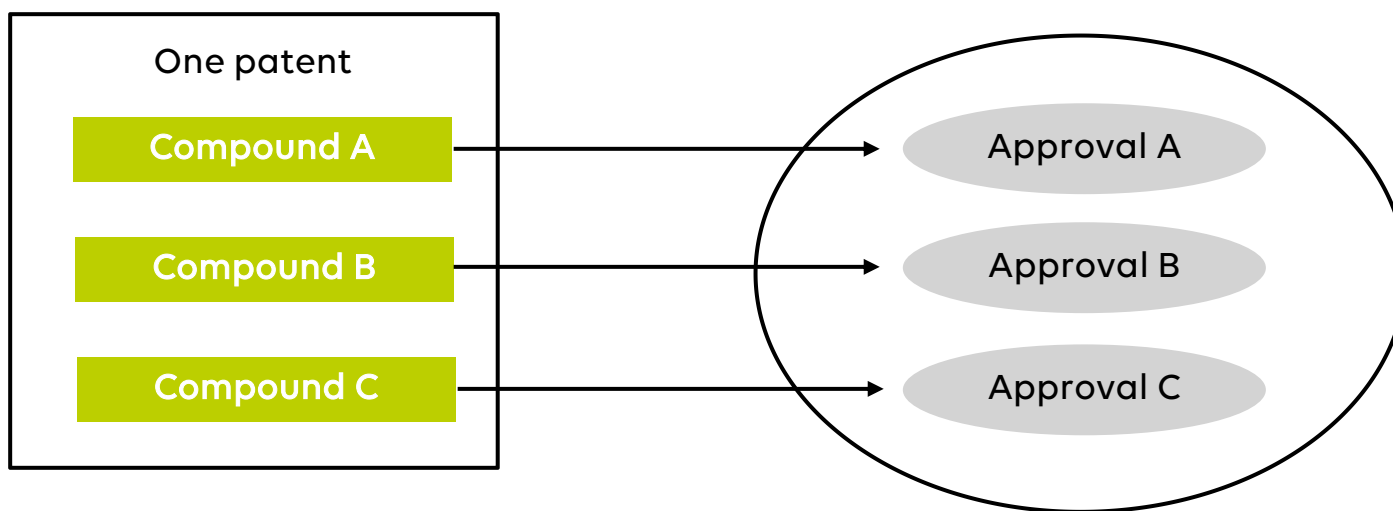
- PTE is available only for **medicinal products** that require marketing approval under the Pharmaceutical Affairs Act or the Narcotics Control Act, and **agrochemical products** that require registration under the Agrochemicals Management Act.
- PTE 仅适用于依据《药事法》或《麻醉品管理法》取得药品上市许可的**药物**，以及依据《农药管理法》完成登记的**农药产品**。
- PTE is limited to **the first approved medicinal product or the first registered agrochemical product** whose active ingredient is **a new substance**.
- PTE 仅适用于有效成分属于**新物质**的**首次获批药物**或**首次登记农药**。
- Approval or registration of **a salt, isomer, solvate, or crystalline form (polymorph)** of a previously approved or registered substance cannot serve as the basis for PTE, as such forms are **not regarded as new substances**.
- 已获批准或已登记物质的**盐型、异构体、溶剂化物或晶型(多晶型)**不视为新物质，因此针对该等形式取得的批准或登记不得作为 PTE 的依据。
- The regulatory approval or registration must have been obtained after the patent grant, thereby preventing the patentee from working the patented invention during that period.
- 药品上市许可或农药登记必须发生在专利授权之后，致使专利权人在该期间内无法实施专利发明。

2. PTE Eligibility Requirements (2) 韩国专利期限延长 (PTE) 适用要件 (2)

- Patent Requirements 专利要件
 - The patent must claim **a substance, a manufacturing process, a use, or a composition** relating to the approved or registered product.
 - 相关专利的权利要求必须涉及经批准或登记产品的**物质、制造方法、用途或组合物**。
 - Patents directed to **intermediates** or **catalysts** used in the manufacture of the approved or registered product, or to **manufacturing equipment**, are not eligible for PTE.
 - 对于涉及经批准或登记产品制造过程中所使用的**中间体、催化剂或制造设备**的专利，不得获得 PTE。
 - The patent must be valid and in force.
 - 该专利必须在有效存续期间内。

3. Key Considerations for PTE Eligibility (1) PTE 适用中的重要考量因素 (1)

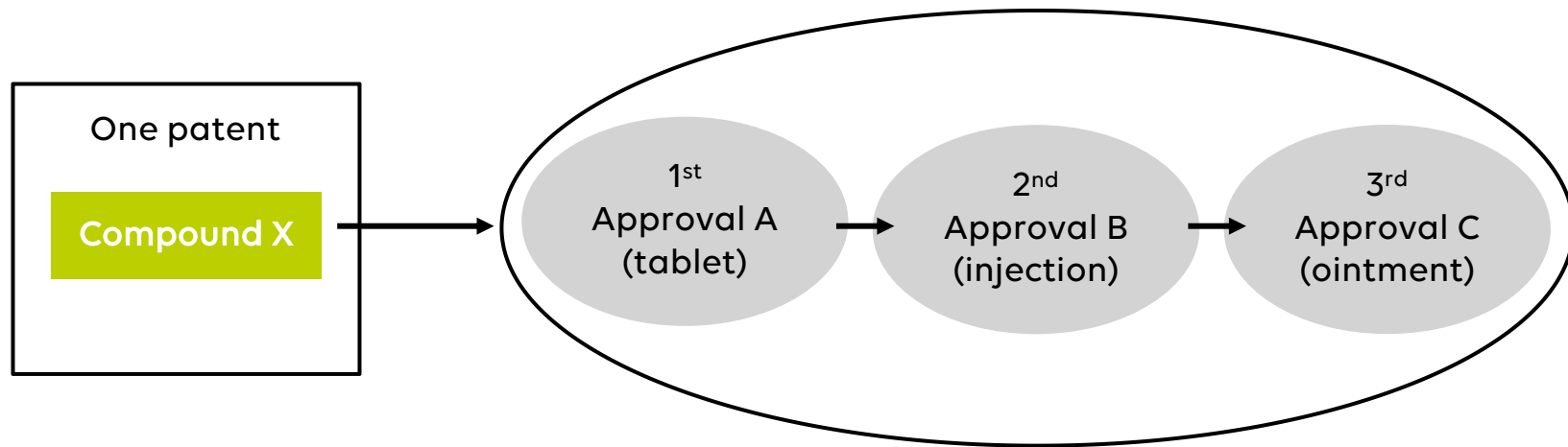
- Where multiple marketing approvals have been obtained for different active ingredients covered by a single patent, **only one approval may be selected as the basis for PTE, and only one PTE may be granted per patent.**
- 如果针对一件专利所涵盖的不同有效成分分别取得了多个药品上市许可，则**仅可选择其中一个药品上市许可作为专利期限延长 (PTE) 的申请依据，且同一专利仅可获得一次专利期限延长 (PTE)。**



PTE may be requested on the basis of one of Approval A, Approval B or Approval C.
可基于批准A、批准B或批准C中的任意一个申请专利期限延长 (PTE)。

3. Key Considerations for PTE Eligibility (2) PTE 适用中的重要考量因素 (2)

- Where multiple marketing approvals have been obtained for the same active ingredient, **only the first approval is eligible as the basis for PTE, and only one PTE may be granted per patent.**
- 针对同一有效成分取得了多个药品上市许可，**仅首次取得的药品上市许可可以作为专利期限延长 (PTE) 的申请依据，且同一专利仅可获得一次专利期限延长 (PTE)。**

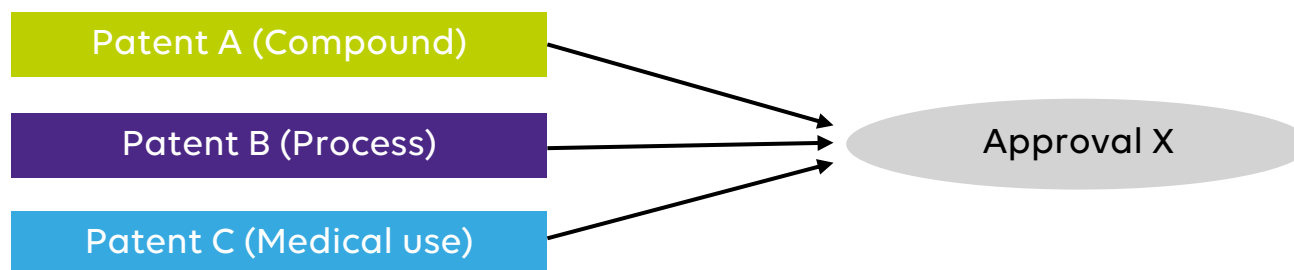


PTE may be requested only on the basis of the first approval, Approval A.
仅可基于首次批准A申请专利期限延长 (PTE)。

3. Key Considerations for PTE Eligibility (3) PTE 适用中的重要考量因素 (3)

- Where multiple patents relate to a single marketing approval,
- 如果一项药品上市许可同时涉及多件专利,

Before July 22, 2025 2025年7月22日前	On or after July 22, 2025 2025年7月22日起
PTE was available for multiple patents. 可针对多件专利适用专利期限延长 (PTE)。	PTE is available for only one patent. 仅可针对一件专利适用专利期限延长 (PTE)。



PTE may be requested for one of Patent A, Patent B, or Patent C.
可针对专利A、专利B或专利C中的一项申请专利期限延长 (PTE)。

4. Extendable Term 可延长期限

- The patent term may be extended by **up to 5 years**.
- 专利期限**最长可延长5年**。
- **Effective as of July 22, 2025**, the total patent term, including the extended term, may not exceed 14 years from the date of the relevant marketing approval or registration (**14-year cap**).
- **自2025年7月22日起**，包含延长期在内的专利总期限，自相关药品上市许可或登记之日起不得超过14年 (**14年上限**)。
- The extendable term is calculated based on:
- 可延长期限以下列期间为基础进行计算：
 - The period of **clinical trials conducted in Korea**; and the period of the **administrative review process** required to obtain marketing approval or registration.
 - **在韩国进行的临床试验期限**；以及取得药品上市许可或登记所需的**行政审查程序**期间。
 - Periods attributable to the applicant, such as the time required to supplement documents, are excluded from the extendable term.
 - 因申请人原因产生的期间，例如补充资料所需期间，不计入可延长期限。
 - **Clinical trial periods conducted outside Korea are not counted.**
 - **在韩国境外进行的临床试验期限不予计算。**

5. PTE Filing Requirements 专利期限延长 (PTE) 申请要求

- Applicant 申请人
 - The applicant for PTE must be **the patentee**.
 - 专利期限延长 (PTE) 的申请人必须为**专利权人**。
- Timing 申请期限
 - A PTE application must be filed **within 3 months from the date of the relevant marketing approval and at least 6 months before the original patent expiry date**.
 - 专利期限延长 (PTE) 申请必须**自相关药品上市许可之日起3个月内提出，并且必须在原专利期限届满日前至少6个月提出**。
- Marketing Approval Holder 药品上市许可持有人
 - Where the marketing approval holder is not the patentee, the marketing approval holder must be registered as **an exclusive or non-exclusive licensee of the patent**.
 - 如果药品上市许可持有人并非专利权人，则该药品上市许可持有人必须登记为**该专利的独占许可人或普通许可人**。

6. Scope of PTE Protection 延长后专利权的保护范围

- Article 95 of the Korean Patent Act 《韩国专利法》第95条
 - The scope of an extended patent is limited to the approved product and its approved use.
 - 延长后专利权的保护范围仅限于经批准的产品及其获批用途。

Marketing Approval Underlying the PTE

Approved Product: Compound A

Approved Use: Treatment of Disease X

Claims of the Extended Patent

Claim 1: Compound A, B, or C

Claim 2: A pharmaceutical composition for treating Disease X, Y, or Z, comprising the compound of claim 1

Although PTE has been granted for Claims 1 and 2 in their entirety, during the extended term, the scope of protection of both claims is limited to Compound A for the treatment of Disease X. 虽然专利期限延长 (PTE) 已就权利要求1和权利要求2整体获得授权, 但在延长期限内, 两项权利要求的保护范围均仅限于用于治疗疾病X的化合物A。

II. Recent Korean Court Cases on PTE 韩国专利期限延长 (PTE) 最新判例



Recent Korean Court Cases on PTE by Topic

韩国专利期限延长 (PTE) 最新判例专题

1

PTE Eligibility Requirement 适用要件

- Case 1: PEGylated Interferon Is Not a “New Substance” for PTE
- 案例 1: 聚乙二醇化干扰素并非 PTE 意义上的“新物质”

2

Scope of PTE Protection: Products 保护范围: 物质

- Case 2: Salt Changes Do Not Avoid PTE Protection
- 案例 2: 盐型变更不影响 PTE 保护范围
- Case 3: Solvates Do Not Avoid PTE Protection
- 案例 3: 溶剂化物不影响 PTE 保护范围

3

Scope of PTE Protection: Use 保护范围: 用途

- Case 4: PTE Protection Is Not Limited to the First Approved Indication
- 案例 4: PTE 保护范围不限于首次获批适应症

Case 1: PEGylated Interferon Is Not a "New Substance" for PTE (1)

案例 1: 聚乙二醇化干扰素并非 PTE 意义上的“新物质” (1)

Supreme Court Decision 2021 Hu 11070 (Jul. 25, 2024)

- Facts 案情

- Interferon beta- 1a (Avonex®) had previously been approved for the treatment of relapsing multiple sclerosis (RMS).
- 干扰素 beta- 1a (Avonex®) 此前已获批准用于治疗复发型多发性硬化症。
- Subsequently, PEGylated interferon beta- 1a (Plegridy®) was approved for the same indication.
- 此后，聚乙二醇化干扰素 beta- 1a (Plegridy®) 获批用于相同适应症。
- A PTE application based on Plegridy® was rejected, and the applicant appealed to the courts.
- 基于 Plegridy® 提出的专利期限延长 (PTE) 申请被驳回，申请人随后提起诉讼。

- Key Issue 争议焦点

- Whether PEGylated interferon beta-1a qualifies as a "new substance" for PTE purposes.
- 聚乙二醇化干扰素 beta- 1a 是否属于 PTE 意义上的“新物质”。

Case 1: PEGylated Interferon Is Not a "New Substance" for PTE (2)

案例 1: 聚乙二醇化干扰素并非 PTE 意义上的 "新物质" (2)

Supreme Court Decision 2021 Hu 11070 (Jul. 25, 2024)

- Supreme Court Holding 最高法院判定
 - PEGylated interferon beta- 1a does not qualify as a "new substance."
 - 聚乙二醇化干扰素 beta- 1a 不属于"新物质"。
 - The Supreme Court reversed the IP High Court's decision, which had recognized PEGylated interferon beta- 1a as a new substance.
 - 最高法院推翻了知识产权高等法院关于聚乙二醇化干扰素 beta- 1a 属于"新物质"的认定。
- Supreme Court Reasoning 最高法院判决理由
 - The therapeutic effect derives from interferon beta- 1a, not the PEG moiety.
 - 其治疗效果来源于干扰素 beta- 1a, 而非PEG部分。
 - PEGylation merely alters the pharmacokinetic properties of interferon beta- 1a, including its half-life.
 - 聚乙二醇化仅改变了干扰素 beta- 1a 的药代动力学特性, 包括其半衰期。
 - Therefore, PEGylated interferon beta- 1a is not a new substance distinct from the previously approved interferon beta- 1a.
 - 因此, 聚乙二醇化干扰素 beta- 1a 并非区别于已获批准的干扰素 beta- 1a 的新物质。

Case 2: Salt Changes Do Not Avoid PTE Protection (1)

案例 2: 盐型变更不影响 PTE 保护范围 (1)

Supreme Court Decision 2017 Da 245798 (Jan. 17, 2019)

- Facts 案情

- PTE was granted based on the marketing approval of Vesicare® (active ingredient: **solifenacin succinate**) for the treatment of overactive bladder symptoms.
- 基于 Vesicare® (有效成分: **琥珀酸索利那新** (solifenacin succinate)) 用于治疗膀胱过度活动症症状的药品上市许可, 相关专利获得了专利期限延长 (PTE)。
- A generic manufacturer obtained marketing approval for A-Care® (active ingredient: **solifenacin fumarate**) for the same indication, after the original patent term had expired but during the extended term.
- 某仿制药企业就相同适应症取得了 A-Care® (有效成分: **富马酸索利那新** (solifenacin fumarate)) 的药品上市许可, 该许可取得于原专利期限届满后但在延长期限内。
- The patent owner filed a patent infringement action against the generic manufacturer.
- 专利权人随后对该仿制药企业提起专利侵权诉讼。

- Key Issue 争议焦点

- Whether an extended patent covers a product containing a different salt form.
- 不同盐型的产品是否落入延长后专利权的保护范围。

Case 2: Salt Changes Do Not Avoid PTE Protection (2)

案例 2: 盐型变更不影响 PTE 保护范围 (2)

Supreme Court Decision 2017 Da 245798 (Jan. 17, 2019)

- Supreme Court Holding 最高法院判定
 - The extended patent covers a product containing a different salt form.
 - 含有不同盐型的产品仍落入延长后专利权的保护范围。
- Supreme Court Reasoning 最高法院判决理由
 - The difference between solifenacin succinate and solifenacin fumarate is merely a change in salt form that can be readily selected by a person skilled in the art.
 - 琥珀酸索利那新 (solifenacin succinate) 与富马酸索利那新 (solifenacin fumarate) 之间的差异仅在于盐型变更，而该等变更属于本领域技术人员容易作出的选择。
 - The two products are substantially identical in their therapeutic effect and approved use, both deriving from the same active moiety, solifenacin.
 - 两者均来源于相同的活性基团索利那新 (solifenacin)，且其治疗效果及获批用途实质相同。
 - Accordingly, a product containing solifenacin fumarate falls within the scope of the PTE granted based on solifenacin succinate.
 - 因此，含有富马酸索利那新 (solifenacin fumarate) 的产品落入基于琥珀酸索利那新 (solifenacin succinate) 获得的专利期限延长 (PTE) 的保护范围。

Case 2: Salt Changes Do Not Avoid PTE Protection (3)

案例 2: 盐型变更不影响 PTE 保护范围 (3)

Supreme Court Decision 2017 Da 245798 (Jan. 17, 2019)

- Significance 意义

- Before this decision, it was generally understood that, based on Article 95 of the Korean Patent Act, a salt-changed product would fall outside the scope of an extended patent, and generic companies often launched such products after the expiration of the original patent term despite the remaining PTE term.
- 在本案判决之前，基于《韩国专利法》第95条，普遍认为改变盐型的产品不属于延长后专利权的保护范围，因此，尽管 PTE 期间尚未届满，仿制药企业仍经常在原专利期限届满后推出此类产品。
- In this decision, the Supreme Court clarified that **a mere change in salt form does not avoid PTE protection** where the products are substantially identical in their active moiety, the therapeutic effect, and approved use. The decision significantly strengthened PTE protection in Korea and marked a turning point in generic launch strategies.
- 在本案中，最高法院明确指出，如果相关产品的活性基团、治疗效果及获批用途实质相同，则**仅因盐型变更并不能规避 PTE 保护**。该判决显著地强化了韩国对专利期限延长 (PTE) 的保护，并成为仿制药上市策略的重要转折点。

Case 3: Solvates Do Not Avoid PTE Protection (1)

案例 3: 溶剂化物不影响 PTE 保护范围 (1)

IP High Court Decision 2023 Heo 13438 (Oct. 23, 2024)

- Facts 案情

- PTE was granted based on the marketing approval of Lixiana® (active ingredient: **edoxaban tosylate hydrate**).
- 基于Lixiana® (有效成分: **依度沙班甲苯磺酸盐水合物** (edoxaban tosylate hydrate))的药品上市许可, 相关专利获得了专利期限延长 (PTE)。
- A generic manufacturer filed a defensive confirmation-of-scope action, seeking a declaration that **edoxaban propylene glycol solvate** (a solvate formed by edoxaban free base and propylene glycol at a 2:1 molar ratio) does not fall within the scope of the extended patent.
- 某仿制药企业提起防御性 (消极) 权利范围确认审判, 请求确认**依度沙班丙二醇溶剂化物** (**edoxaban propylene glycol solvate**) (即由游离态依度沙班与丙二醇按 2:1 摩尔比形成的溶剂化物) 不属于延长后专利权的保护范围。
- The generic manufacturer also argued that the patentee had excluded solvates by amending the claims from a solvate to a hydrate form during prosecution.
- 该仿制药企业还主张, 专利权人在审查过程中通过将权利要求由溶剂化物 (**solvate**) 补正为水合物 (**hydrate**), 将溶剂化物排除在专利保护范围之外。

- Key Issue 争议焦点

- Whether an extended patent covers a product containing a different solvate form.
- 不同溶剂化物形式的产品是否落入延长后专利权的保护范围。

Case 3: Solvates Do Not Avoid PTE Protection (2)

案例 3: 溶剂化物不影响 PTE 保护范围 (2)

IP High Court Decision 2023 Heo 13438 (Oct. 23, 2024)

- IP High Court Holding 知识产权高等法院判定
 - Edoxaban propylene glycol solvate falls within the scope of the extended patent.
 - 依度沙班丙二醇溶剂化物 (edoxaban propylene glycol solvate) 属于延长后专利权的保护范围。
- IP High Court Reasoning 知识产权高等法院判决理由
 - Propylene glycol is a well-known solvate-forming agent.
 - 丙二醇 (propylene glycol) 是本领域公知的溶剂化物形成剂。
 - Edoxaban propylene glycol solvate has substantially the same therapeutic effect and use as edoxaban tosylate hydrate, and could be readily selected by a person skilled in the art as an alternative solid form of edoxaban.
 - 依度沙班丙二醇溶剂化物 (edoxaban propylene glycol solvate) 与依度沙班甲苯磺酸盐水合物 (edoxaban tosylate hydrate) 在治疗效果及用途方面实质相同，且本领域技术人员容易将其作为依度沙班的替代固体形式加以选择。
 - The prosecution history does not show that solvates were intentionally excluded from the scope of the patent. The amendment to a hydrate form was made for claim clarity, not to exclude other solvate forms.
 - 从审查历史来看，并无证据表明溶剂化物被有意排除在专利保护范围之外。将权利要求补正为水合物是为了满足权利要求明确性的要求，而非排除其他溶剂化物形式。

Case 4: PTE Protection Is Not Limited to the First Approved Indication (1)

案例 4: PTE 保护范围不限于首次获批适应症 (1)

IP High Court Decisions: 2024 Heo 13541 (Jan. 23, 2025); 2024 Heo 13824 (May 27, 2025); 2024 Heo 12890 (Aug. 13, 2025); *etc.*

• Facts 案情

- PTE was granted based on the marketing approval of K-CAB® (active ingredient: tegoprazan) for the treatment of **the initial indications** of erosive and non-erosive gastroesophageal reflux disease (GERD).
- 基于K-CAB® (有效成分: 替戈拉生 (tegoprazan)) 用于治疗糜烂性及非糜烂性胃食管反流病 (GERD) 这一**首次获批适应症**的药品上市许可, 相关专利获得了专利期限延长 (PTE)。
- Later, the marketing approval of K-CAB® was expanded to include **additional indications**, such as gastric ulcer and maintenance therapy following treatment of erosive GERD.
- 此后, K-CAB® 的药品上市许可进一步扩大至胃溃疡治疗以及糜烂性GERD治疗后的维持治疗等**追加适应症**。
- A generic manufacturer filed a defensive confirmation-of-scope action, seeking a declaration that a pharmaceutical composition comprising tegoprazan for the treatment of **a subsequently approved indication** does not fall within the scope of the extended patent.
- 某仿制药企业提起防御性 (消极) 权利范围确认审判, 请求确认包含替戈拉生 (tegoprazan) 且用于治疗**后续获批适应症**的药学组合物不属于延长后专利权的保护范围。

• Key Issue 争议焦点

- Whether the scope of an extended patent covers later-approved indications that were not included in the marketing approval on which the PTE was based.
- 延长后专利权的保护范围是否及于未包含在 PTE 依据药品上市许可中的后续获批适应症。

Case 4: PTE Protection Is Not Limited to the First Approved Indication (2)

案例 4: PTE 保护范围不限于首次获批适应症 (2)

IP High Court Decisions: 2024 Heo 13541 (Jan. 23, 2025); 2024 Heo 13824 (May 27, 2025); 2024 Heo 12890 (Aug. 13, 2025); *etc.*

- IP High Court Holding 知识产权高等法院判定
 - A later-approved indication may fall within the scope of an extended patent if it is substantially identical in therapeutic effect and use.
 - 如果后续获批适应症在治疗效果及用途方面实质相同，则其可能属于延长后专利权的保护范围。
- IP High Court Reasoning 知识产权高等法院判决理由
 - The “medical use” under patent law is not equivalent to the approved indications under the Pharmaceutical Affairs Act.
 - 专利法意义上的“医药用途”并不等同于《药事法》规定的获批适应症。
 - The scope of PTE protection should not depend on which indication was included in the marketing approval underlying the PTE, because this would result in different levels of protection for the same patented invention.
 - PTE 保护范围不应取决于作为 PTE 依据的药品上市许可中包含哪一种适应症，否则将导致同一专利发明获得不同程度的保护。
 - The later-approved indication was substantially identical to the initial indications underlying the PTE in terms of therapeutic effect and use, both involving the treatment of acid-related diseases through gastric acid suppression.
 - 后续获批适应症在治疗效果及用途方面与作为 PTE 依据的首次适应症实质相同，两者均通过抑制胃酸分泌治疗酸相关疾病。

III. Key Takeaways

要点总结



Key Takeaways

要点总结

For Patent Owners 专利权人

- Choose the patent for PTE strategically under the 2025 amendments (14-year cap and one-patent-per-approval rule).
- 根据2025年修法，战略性地选择申请专利期限延长 (PTE) 的专利 (14年期限上限及“一项上市许可对应一件专利”的规则)。
- Recent court decisions may provide broader PTE protection than previously expected.
- 近期法院判例显示，PTE 的保护范围可能比以往预期更广。

For Generic Companies 仿制药企业

- Traditional design-around strategies, such as changing the salt form, solvate form, or indication, may not be sufficient to avoid PTE protection.
- 传统的规避设计策略，例如改变盐型、溶剂化物或适应症，可能不足以规避 PTE 保护。



Thank You.

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