

用法用量型用途发明的 专利保护困局

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01 用法用量医药用途专利性判断标准

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法域	主要法律依据 / 规则	授权难度	审查标准
中国 CNIPA	《专利审查指南》第二部分第十章 5.4；专利法第22条第2款/第3款	极难（基本不可能）	一般不具备新颖性；仅当用法特征对“制药过程”（原料、步骤、产品形态/成分）产生限定作用时例外，即便通过新颖性，创造性亦常被否定
美国 USPTO	35 U.S.C. §101 / §103；MPEP 关于 method-of-treatment 权利要求	可能（创造性门槛高）	给药方案被现有技术公开时→不具备；与现有技术有事实差异且无合理成功预期→可具备新创性
欧洲 EPO	EPC 第54(4)/(5)条；第53(c)条；G 2/08 (Dosage regime/ABBOTT) 确立可专利性	可能（创造性门槛高）	只要该用途本身未被现有技术直接、明确公开，原则上可具备新颖性；创造性门槛高，特定剂量默认属“obvious to try”；需证明预料不到的技术效果
日本 JPO	《特许·实用新型审查基准》医药用途发明篇；用途发明须以新用途为构成要素	可能（创造性门槛高）	优化用法用量（如降低毒性或改善药效）倾向于认定“常规开发”，除非能证明该用法用量带来了“预料不到的效果”新用法用量克服了现有技术中存在的偏见，则更容易获得认可

四法域用法用量医药用途专利审查标准

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CNIPA

- 《专利审查指南》第二部分第十章 5.4；专利法第22条第2款
- 给药剂量、时间间隔等仅体现用药过程的特征，通常不属于制药用途的技术特征
- 一般不具备新颖性；仅当用法特征对“制药过程”（原料、步骤、产品形态/成分）产生限定作用时例外
- 即便通过新颖性，创造性亦常被否定

Case 1:第568709号无效决定（2024年度）

ZL200980104713.X

【权利要求】地加瑞克在制备治疗受试者转移期前列腺癌的药物中的应用，所述治疗包括初次剂量160–320mg、之后每20–36天一次维持剂量60–160mg，且受试者治疗前基线血清碱性磷酸酶（S-ALP） $\geq$ 约150IU/L。

【现有技术】公开地加瑞克用于前列腺癌治疗；本领域公知前列腺癌分期及“转移期”的临床意义

【无效决定】初次剂量、维持剂量、给药频次仅涉及用药方法，对医药用途不具有限定作用；“转移期前列腺癌”及“S-ALP $\geq$ 150IU/L”具限定作用，但基于现有技术启示仍无创造性→专利全部无效

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EPO/UPC

- EPC 第54(4)/(5)条; G 2/08 (Dosage regime/ABBOTT)
- 剂量方案可构成 “特定用途” 而成为新颖性来源
- 原则上可具备新颖性，只要该用途本身未被现有技术直接、明确公开
- 创造性门槛高，特定剂量默认属 “obvious to try” ；需证明预料不到的技术效果

Case2: T 1701/22 (Obesity treatment with semaglutide/NOVO NORDISK) of 16.01.2025

- Claim 1 of EP2866825. A composition comprising the GLP-1 agonist semaglutide and one or more pharmaceutically acceptable excipients for use in the prevention or treatment of obesity, wherein said use comprises administration of said GLP-1 agonist **in an amount of at least 0.7 mg per week**; and said composition is in the form of an aqueous formulation with pH between 3 and 10.
- **【EPO' Argument】** The claimed dosage regimen is consistent with the range proposed (0.1 to 1.6 mg/week) in D10 (the closest prior art), with no apparent difference in effect, as the claimed dose of **at least 0.7 mg/week overlaps to a great extent with the dose range proposed in document D10, i.e. the upper half of the 0.1 to 1.6 mg/week**, inter alia for the treatment of obesity. In line with the dose-dependent effects reported in the common general knowledge for the whole class of GLP-1 receptor agonists (e.g. document D4, page 596, left-hand column, third paragraph), Figure 5 of the patent in suit **shows a dose-dependent effect of semaglutide**. Thus the claimed **range of at least 0.7 mg/week is arguably not associated with a surprising effect**.

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USPTO

- 35 U.S.C. §101/ § 102 / §103; MPEP 关于 method-of-treatment 权利要求
- 用法用量型医药用途，可能被认定为“不可专利的客体”（Mayo v. Prometheus 案）
- 与现有技术有事实差异或未被现有技术公开，具有新颖性
- 创造性门槛高：“调整剂量和给药频率”被认为是制药领域的常规实验。除非用法用量方案产生了预料不到的效果

Case 3: Mayo Collaborative Services v. Prometheus Laboratories, Inc. (2012).

Claim 1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

仅仅在自然规律（如药物代谢物浓度与疗效/毒性之间的关联）之上附加“常规、已知”的步骤（如给药和检测），不足以使该权利要求成为可专利的客体

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JPO

- 《特许·实用新型审查基准》医药用途发明篇；用途发明须以新用途为构成要素
- “用法又は用量で特定しようとする医薬発明” 被承认为医药用途发明的一种
- 与现有技术有事实差异或未被现有技术公开，具有新颖性
- 优化用法用量（如降低毒性或改善药效）倾向于认定“常规开发”，除非能证明该用法用量带来了“预料不到的效果” 新用法用量克服了现有技术中存在的偏见，则更容易获得认可

Case 4: Example from JPO Examination Guidelines

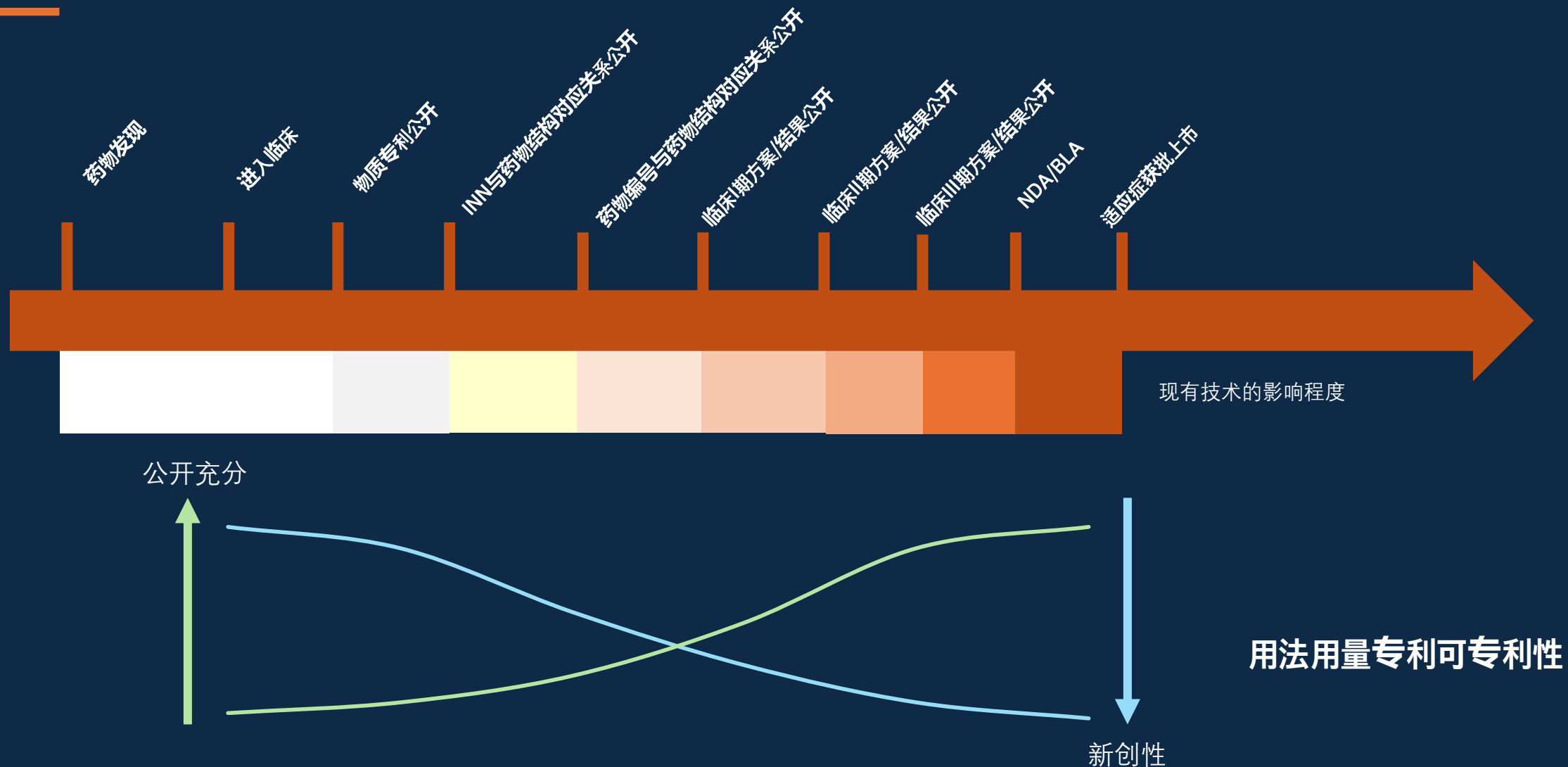
- The invention relates to a compound for the treatment of asthma, which is administered **at a dose of 30 to 40 g/kg once every three months.**
- The prior art cited against the inventive step disclosed the use of the same compound for the treatment of the same disease, but **at a dosage of 1 g/kg daily.** It was further known that **the administration regimen of the prior art (low daily dose) led to side effects and a recurrence of symptoms upon cessation of treatment.**
- The description of the invention mentions, and further experimentally demonstrates, that, contrary to what would have been expected given the side effects associated with a low daily dose and the loss of efficacy when stopping the daily treatment, the invention (administration of the compound at a 30 to 40-fold higher dosage once every three months) **leads to improved efficacy over time, including upon cessation of treatment, and to reduced side effects when compared to the administration of a low daily dose.**
- The unpredictable nature of these advantages allows inventive step to be acknowledged.

02 自主公开的技术信息的管理与控制

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各国注册法规强制公开的要求

维度	中国	美国	欧盟	日本
是否强制公开	已取得许可的药物临床试验（BE/PK/I-IV 期）强制登记与公示；IIT、企业自行 IV 期无强制	适用临床试验（ACT）强制；药物 Phase 1 一般不属于 ACT	强制：所有在 EU/EEA 的药品干预性试验，未经 CTIS 授权不得启动	强制：双轨——治験（薬機法施行規則第 272 条之 2）+ 特定臨床研究（臨床研究法）
公开网站	药物临床试验登记与信息公示平台 www.chinadrugtrials.org.cn ChiCTR: www.chictr.org.cn	ClinicalTrials.gov	CTIS: euclinicaltrials.eu 存量库: clinicaltrialsregister.eu CSR: clinicaldata.ema.europa.eu	jRCT: jrct.mhlw.go.jp 横向检索: rctportal.mhlw.go.jp
登记时限	临床试验获批后 1 个月内预登记；首例入组前完成首次提交公示	首例入组后 21 个日历日内	提交 CTIS 申请后于首个成员国决定即公开	启动前须完成 jRCT 登记
公开内容（登记）	结构化字段：试验药物基本信息、方案基本信息（设计/入排/给药方案概要）、研究者、机构等	结构化字段：干预描述、分组、终点状态、地点等	结构化字段 + 方案（含方案摘要）pdf+ 受试者面向文件（如ICF）pdf	WHO 登记数据集 24 项全项必填
用法用量是否须必须披露	正常需要公开，但可向CDE要求不公开	可以不公开	CTIS 结构化字段可不公开具体用法用量，文件（如ICF）中可涂黑（CCI）	部分——概要级可见，完整方案不公开

02 自主公开的技术信息的管理与控制

试验专业题目 HRS-7172 联合抗肿瘤治疗在实体瘤参与者中的安全性、耐受性及有效性的开放、多中心IB/II期临床研究

试验药	序号	名称	用法
	1	中文通用名:HRS-7172片 英文通用名:HRS-7172 Tablets 商品名称:NA	剂型:片剂 规格:10mg/片; 50mg/片 用法用量:按方案规定使用 用药时程:按方案规定使用
	2	中文通用名:注射用紫杉醇 (白蛋白结合型) 英文通用名:Paclitaxel for Injection (Albumin Bound) 商品名称:艾越	剂型:注射剂 规格:100mg/瓶, 1瓶/盒 用法用量:按方案规定使用 用药时程:按方案规定使用
	3	中文通用名:注射用盐酸吉西他滨 英文通用名:Gemcitabine Hydrochloride for Injection 商品名称:英择	剂型:注射剂 规格:1.0g/支, 5支/盒 用法用量:按方案规定使用 用药时程:按方案规定使用

02 自主公开的技术信息的管理与控制



National Library of Medicine
National Center for Biotechnology Information

An official website of the United States government
[Here's how you know](#)

Find Studies

Study Basics

Submit Studies

Data and API

Policy

About

My Saved Studies (0)

Study Type *

ICMJE

Interventional

Study Phase *

ICMJE

Phase 2

Study Design *§

ICMJE

Allocation

Randomized

Interventional Model

Parallel Assignment

Masking

Double (Participant, Investigator)

Primary Purpose

Treatment

Condition *

ICMJE

- Atrial Fibrillation

Intervention *

ICMJE

- Drug: **BAY 3670549**
 - intravenous (IV) treatment
- Other: Placebo
 - intravenous (IV) treatment

Study Arms *

ICMJE

- Experimental: **BAY 3670549**
 - Interventions:
 - Drug: BAY 3670549
- Placebo Comparator: Placebo
 - Interventions:
 - Other: Placebo

clinicaltrials.gov

02 自主公开的技术信息的管理与控制

[22961] A placebo-controlled, parallel-group, double blind, randomized, multi-cohort Phase 2 study to investigate efficacy, safety, tolerability, pharmacodynamics and pharmacokinetics of BAY 3670549 in adult participants with atrial fibrillation.

EUCT number: 2025-523807-31-00

Protocol code: 22961

Download clinical trial

Summary Full trial information Trial Documents Trial results Locations and contact points

Refer to [this document](#) for an explanation of this section.

Protocol, Synopsis of the protocol, Summary of product characteristics (SmPC)

Title	Document Type	Language	File type
D1_Protocol_EN_Public_2025-523807-31-00	Protocol (for publication)	English	PDF
D4_Subject_Questionnaires_Sponsor_Statement_Licensed_PROs_Public_EN	Protocol (for publication)	English	PDF

Belgium - Authorised, recruitment pending

Title	Document Type
K2_Recruitment_material_Public_Patient_Leaflet_BE_EN	Recruitment arrangements (for publication)
K2_Recruitment_material_Public_Patient_Leaflet_BE_FR	Recruitment arrangements (for publication)
K2_Recruitment_material_Public_Patient_Leaflet_BE_NL	Recruitment arrangements (for publication)
K1_Recruitment_arrangements_Public_BE_EN	Recruitment arrangements (for publication)
L1_SIS_and_ICF_Core_Public_BE_EN	Subject information and informed consent form (for publication)
L1_SIS_and_ICF_Core_Public_BE_FR	Subject information and informed consent form (for publication)
L1_SIS_and_ICF_Core_Public_BE_NL	Subject information and informed consent form (for publication)

You and your investigator will not know which drug you will be taking. But your investigator can find out in case of an emergency.

BAY 3670549 will be given as an infusion into one of your veins. You will receive BAY 3670549 on a single day **CCI**

Dose escalation

The study is conducted in three consecutive patient groups, each receiving a different dose. The highest allowed dose is pre-specified in the study protocol, and the dose for each patient group is determined based on this maximum. After the first group has completed treatment, all data collected will be reviewed by the study team to decide on the doses to be tested in one to two additional patient groups.

The first group of approximately 72 participants will receive **CCI** of BAY 3670549. If this dose works as expected, the next group of participants will receive a different dose of BAY 3670549. Doses may need to be increased or lowered based on the results observed, for example, if the amount of study drug measured in the blood is unexpectedly low, or if side effects occur.

03 用法用量型专利的破局与利益平衡

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A 类 · 新规律发现或违背现有认知

发现剂量-效应关系中违背既有认知的新规律。

B 类 · 人群 / 场景变化导致用法用量的变化

针对特定患者群或临床场景设计差异化给药方案。

C 类 · 策略性延续（常青化）

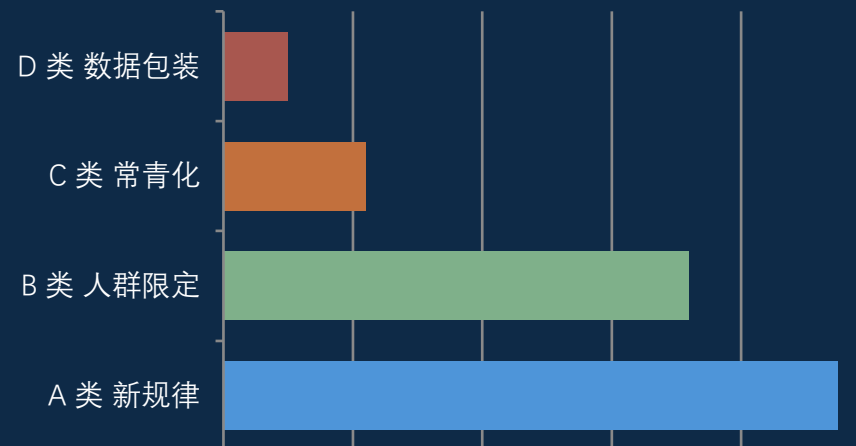
在现有专利基础上做微小剂量 / 给药调整，无新的科学发现。

D 类 · 注册性数据的策略性利用

把临床试验中自然得出的方案策略性申请专利。

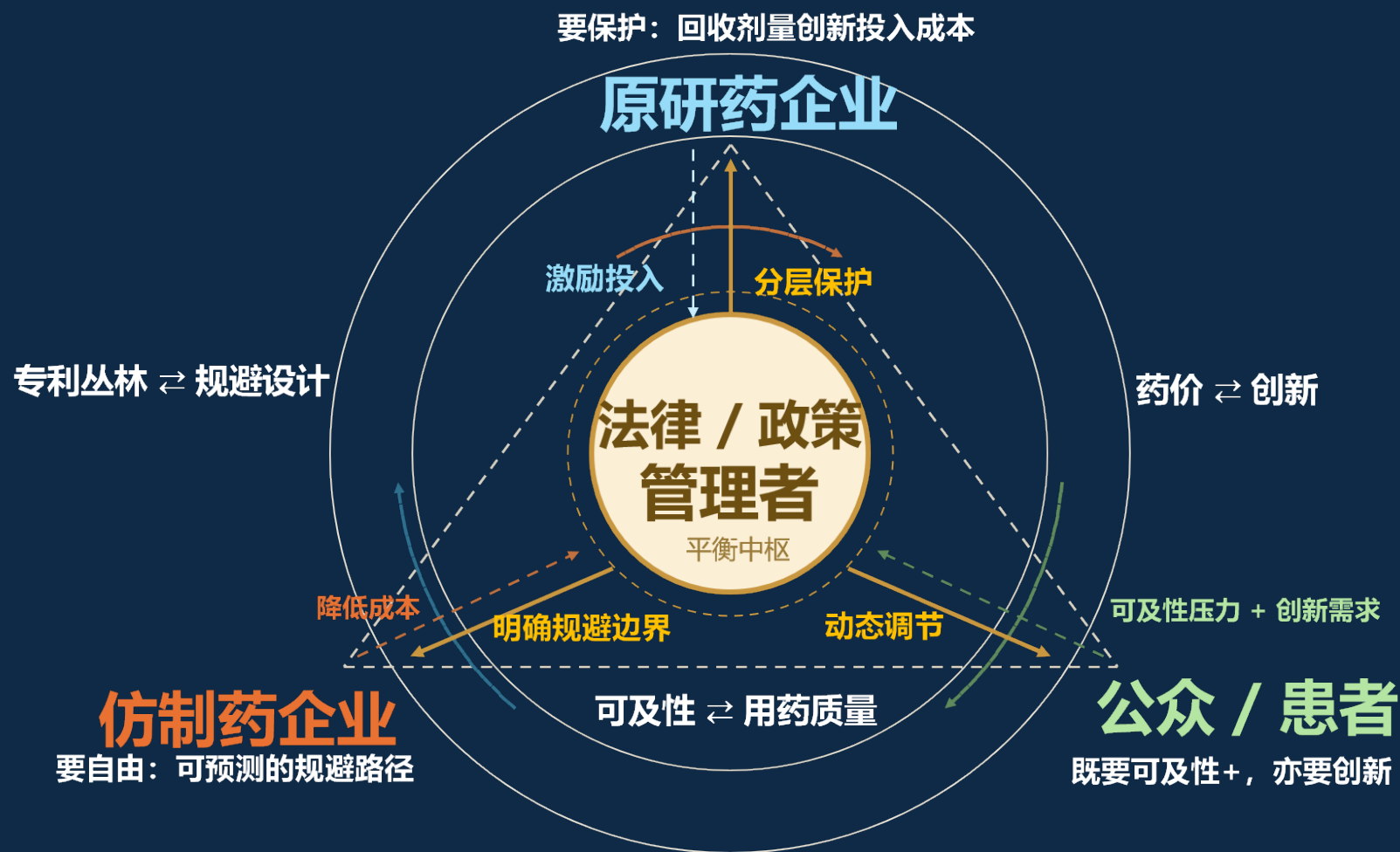
创新实质梯度

技术贡献（定性）



用法用量创新的四类分型

03 用法用量型专利的破局与利益平衡



Thanks!