

IP SERVICES IN RUSSIA, EURASIA, UAE AND CIS COUNTRIES



PROTECTING TWO PARTS OF THE WHOLE:
IDEA AND RIGHT

COMPULSORY LICENSE COURT CASE STUDY IN RUSSIA AND EURASIA

俄罗斯与欧亚地区法院强制许可案例研究



In Russian law, the use of a patent without the owner's consent is strictly regulated by the Civil Code of the Russian Federation (CC RF).

1. **National Security and Public Interest (Article 1360 CC RF)**
2. **A compulsory license may be granted by court to a third party** if the patent owner is not effectively using their invention.
3. **Dependent Patents:** If a patent holder cannot use their invention without infringing on an earlier patent, they can sue for a compulsory license if their invention is a **significant technical achievement** with substantial economic advantages.

根据俄罗斯法律，未经专利权人同意使用专利的行为受到《俄罗斯联邦民法典》的严格规制。

1. **国家安全与公共利益**（《俄罗斯联邦民法典》第1360条）
2. 如果专利权人不能有效地使用其发明，法院可以向第三方授予强制许可。
3. **从属专利：**如果专利权人无法在不侵犯在先专利权的情况下使用其发明，且其发明是一项具有重大经济优势的**重大技术成就**，则可以提起诉讼要求获得强制许可。

1. National Security and Public Interest (Article 1360 CC RF)

The Government of the Russian Federation has the right to authorize the use of an invention, utility model, or industrial design without the patent holder's consent.

1. 国家安全与公共利益（《俄罗斯联邦民法典》第1360条）

俄罗斯联邦政府有权在未经专利权人同意的情况下，授权使用发明、实用新型或外观设计。

Criteria:

In cases of **extreme necessity** related to ensuring national defense and state security.

To protect the **life and health** of citizens (e.g., during a pandemic).

Conditions:

The patent holder must be notified as soon as possible.

The owner is entitled to **proportionate compensation** (the methodology for calculation is set by the Government).

适用标准:

涉及确保国防和国家安全的**极端必要情形**。

为保护公民的**生命与健康**（例如，在疫情期间）

适用条件:

必须尽快通知专利权人。

专利权人有权获得**相应补偿**（计算方法由政府制定）。

2. A compulsory license may be granted by court to a third party if the patent owner is not effectively using their invention.

Grounds for Non-use:

Timeline: The patent is not used or is insufficiently used for **4 years** (inventions/ industrial designs) or **3 years** (utility models).

Criteria: The non-use leads to a **shortage** of relevant goods or services on the market.

Applicant's Burden: The person seeking the license must prove they offered a voluntary license agreement to the owner on fair terms but were refused.

2.如果专利权人不能有效地使用其发明，法院可以向第三方授予强制许可。

未实施的理由：

时限： 专利未被使用或未被充分使用的期限为**4年**（发明/外观设计）或**3年**（实用新型）。

标准： 未使用行为导致市场上相关商品或服务出现**短缺**。

申请人责任： 寻求许可的一方必须证明其已向专利权人提出按公平条款签订自愿许可协议但遭到拒绝。

3. Dependent Patents:

If a patent holder cannot use their invention without infringing on an earlier patent, they can sue for a compulsory license if their invention is a **significant technical achievement** with substantial economic advantages.

3. 从属专利:

如果专利权人无法在不侵犯在先专利权的情况下使用其发明，且其发明是一项具有重大经济优势的**重大技术成就**，则可以提起诉讼要求获得强制许可。



General number of compulsory license disputes

Before 2023 the courts heard no more than two of such cases.

In 2023 - 2024 11 disputes were already initiated, and another 14 - between January and October 2025, according to "Inpharma".

In total there are about 40 cases filed in 2023 – 2026.

强制许可争议案件总体数量

直到2023，法院已经考虑了不超过两个类似的案件。

另据《Inpharma》报道，2023 - 2024年已提起11起争议，2025年1月至10月期间又提起14起。

总共有大约40案件在2023-2026中提交。

Result of court cases on compulsory license disputes.

All the cases filed in 2023 and 2024 were judged in favor of plaintiffs, compulsory licenses were granted.

In July 2026, Moscow Court rejected claim for compulsory license for the first time.
Case No. A40-46740/2025

强制许可纠纷案件的结果.

2023年和2024年提起的所有案件均判决原告胜诉，强制许可得以批准。

2026年7月，莫斯科法院首次驳回了关于强制许可的诉讼请求。
案件编号：A40-46740/2025

Ruling of the Constitutional Court of the Russian Federation dated March 12, 2026

IP Protection vs. Right to Life: Finding a Compromise

Ruling of the Constitutional Court of the Russian Federation dated March 12, 2026, No. 13-P "On the Case of Reviewing the Constitutionality of Clause 1, Article 1362 of the Civil Code of the Russian Federation in Connection with the Complaints of JSC Sanofi Russia and Vertex Pharmaceuticals Incorporated."

俄罗斯联邦宪法法院2026年3月12日的 裁决

知识产权保护与生命权：寻求妥协

俄罗斯联邦宪法法院2026年3月12日第13-P号裁定“关于审查《俄罗斯联邦民法典》第1362条第1款合宪性案（因俄罗斯赛诺菲股份公司和福泰制药公司投诉而提起）”。

Background to the Introduction of Compulsory Licensing

Bad faith actions by a rights holder — in particular, by restricting imports to the Russian market or by implementing a pricing policy that involves excessive markups beyond standard economic activity and reasonable economic interest — cannot be deemed acceptable in terms of protecting constitutionally significant values if such actions restrict Russian consumers' access to essential goods, primarily life-critical products (e.g., specific categories of medicines, life-support equipment, etc.).

引入强制许可的背景

权利人的不诚信行为——特别是通过限制对俄罗斯市场的进口，或实施包含超出标准经济活动和合理经济利益之外的超额加价的定价政策——如果此类行为限制了俄罗斯消费者获取基本商品（主要是生命必需产品，如特定类别的药品、生命支持设备等）的途径，则从保护具有宪法重要性的价值角度来看，是不可接受的。

Compulsory Licensing as a Tool for National Security

The court-ordered granting of a compulsory license at the request of an interested party—allowing for the use of a patent alongside with the patent holder—serves as an instrument to adjust the standard regime of exclusive intellectual property rights.

This measure aims to rectify the imbalance between private and public interests in cases of non-use or insufficient use of a patent (which, for instance, has led to shortages of specific products in the Russian market) or the acquisition of unjustifiable economic advantages by the patent holder.

强制许可作为国家安全的工具

应利害关系方请求，法院裁定授予强制许可——允许与专利权人并行使用专利——是调整标准独占性知识产权制度的工具。该措施旨在纠正因专利未使用或未充分利用（例如，

已导致俄罗斯市场特定产品短缺）或专利权人获得不正当经济利益而导致的私人与公共利益之间的失衡。

The purpose of issuing a compulsory license

is to overcome the consequences of the patent holder's behavior, where society suffers—specifically individuals whose lives depend on the exercise of the rights holder's dishonesty.

This applies whether such behavior stems from bad faith, passivity, or objective circumstances coupled with the patent holder's specific subjective attitude (i.e., when their behavior, while formally legal, de facto acquires the characteristics of bad faith)

颁发强制许可的目的

在于克服专利权人行为所造成的后果，即社会——特别是其生命依赖于权利人行使权利的个人——所遭受的损害。无论此类行为源于不诚信、

被动不作为，还是客观情况与专利权人特定主观态度的结合（即，其行为虽然形式上合法，但实际上具有了不诚信的特征），均适用之。

In this case, the objective of the legal system is to empower an entity, having expressed the intent and readiness to manufacture and supply the product, to produce it using methods that replicate the properties and qualities of the original. This ensures the consumer experience remains identical or substantially similar in key parameters.

To the extent that the production process requires the use of patented intellectual property (including materials, components, chemical substances, technologies, and technical solutions), **said entity shall be granted the right to use these results under a compulsory license—strictly within the necessary scope, neither more nor less.**

在此情况下，法律体系的目标是授权一个已表示有意愿并准备好生产和供应产品的主体，使用能够复制原产品特性和质量的方法进行生产。这确保消费者的体验在关键参数上与原始产品相同或实质相似。

在生产过程需要使用专利知识产权（包括材料、组件、化学物质、技术和技术解决方案）的范围内，该主体应被授予在强制许可下使用这些成果的权利——严格限于必要范围内，不多也不少。

Constitutional Court ruled new Evidence Criteria for compulsory license:

- Evidence of Unsatisfied Demand**
- Economic Unjustifiability for
Prices**
- Rationale for Social Significance**
- Readiness of the Compulsory
Licensee**

宪法法院裁定强制许可的新证 据标准:

- 需求未得到满足的证据**
- 价格的经济不合理性**
- 社会意义的理由**
- 强制许可被许可人的准备就绪
状态**

ESTABLISHING PROOF OF UNSATISFIED DEMAND

- To trigger the granting of a compulsory license, the bad faith actions or omissions of the patent holder must occur in conjunction with a **resulting supply shortage of the relevant products and maintain a direct causal link to such a shortage.**
- Indicators of insufficient supply may include discrepancies between actual delivery volumes and current demand, regular shipping delays, failure to meet agreed terms, and production disruptions.

确立需求未得到满足的证明

- 为触发强制许可的授予，专利权人的不诚信作为或不作为必须与相关产品的供应短缺同时发生，并**与该短缺保持直接的因果关系。**
- 供应不足的指标可能包括实际交付量与当前需求之间的差异、定期发货延迟、未能满足约定条款以及生产中断。

ESTABLISHING PROOF OF UNSATISFIED DEMAND

- It is insufficient to merely state that a medicine is unavailable in pharmacies. Evidence must be presented regarding **failed governmental tenders** (specifically, protocols declaring tenders void due to a lack of bids), which directly proves a shortage on a national scale.
- To clarify the extent to which consumer interest in a particular product is currently satisfied—and how it may be satisfied in the future—through the actions of the patent holder and the supply of original products, **taking price levels into account.**

确立需求未得到满足的证明

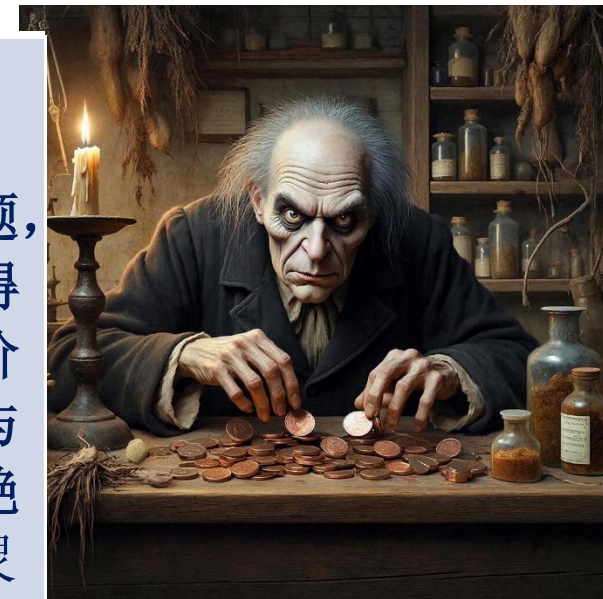
- 仅凭声称某药品在药房无售，不足以作为证据。必须提供关于**失败的公共采购流程**（特别是因缺乏投标而宣布招标无效的协议）的证据，这直接证明了全国范围内的短缺。
- 通过专利权人的行为和原产品的供应，并**考虑价格水平**，以阐明消费者对特定产品的当前需求得到满足的程度，以及未来可能如何得到满足。

ECONOMIC UNJUSTIFIABILITY OF PRICE

- If a patent holder demonstrates a willingness to address a shortage only in conjunction with a rigid and non-negotiable demand for prices that are prohibitively high for consumers, then the underutilization of the invention is directly linked to the patent holder's intent and their absolute control over pricing policy. By employing such an inflexible approach, these rights holders essentially seek to shift the burden of their development and implementation costs (which are typically not officially or reliably verified) onto public budgets or private consumers, while maintaining the opportunity to multiply this compensation across various territorial markets.

价格的经济不合理性

如果专利权人表示愿意解决短缺问题，但前提是必须接受对消费者而言高得令人望而却步的刚性且不可谈判的价格要求，那么发明的未充分利用就与专利权人的意图及其对定价政策的绝对控制直接相关。通过采用这种不灵活的做法，这些权利人实质上试图将其开发和实施成本（通常未经官方或可靠核实）的负担转嫁给公共预算或私人消费者，同时保留在不同地域市场成倍增加这种补偿的机会。



A price comparison between the original drug in the Russian Federation and countries with comparable economies is essential. **If the price in Russia is significantly higher without valid logistical justification, it serves as a compelling argument that the rights holder is abusing its monopoly power.**

将原研药在俄罗斯联邦与具有可比经济体的国家的价格进行比较至关重要。如果俄罗斯的价格在没有有效物流理由的情况下显著偏高，这将成为证明权利人滥用其垄断地位的有力论据。



In Ruling No. 41-P of September 26, 2024, the Constitutional Court of the Russian Federation recognized that orphan diseases are characterized by their lifelong nature and often lack effective treatments, or involve treatments with significantly higher costs compared to common diseases. This ruling highlights the unique burden of such conditions, where medication is crucial yet often financially inaccessible.

Driven by high demand and maintained supply exclusivity, certain goods may face extreme shortage, resulting in disproportionately high pricing. In socially sensitive sectors such pricing cannot remain a matter of indifference to public policy; it necessitates justified regulatory adjustments to prevent abuse and ensure a fair balance of interests between private entities and society in the whole.

在2024年9月26日第41-P号裁定中，俄罗斯联邦宪法法院认定，罕见病的特点是终身性质，通常缺乏有效治疗方法，或者其治疗费用相比常见疾病显著高昂。该裁定强调了此类疾病的独特负担，即药物治疗至关重要，但往往在经济上难以负担。

受高需求和保持供应独占性的驱动，某些商品可能面临极度稀缺，导致定价过高。在社会高度敏感的领域，此类定价不能成为公共政策漠不关心的问题；必须进行合理的监管调整，以防止滥用行为，并确保私人实体与整个社会之间的利益实现公平平衡。

ESTABLISHING INTEREST IN OBTAINING A COMPULSORY LICENSE

- A compulsory license applicant is expected and required to demonstrate a duly presented offer to the **patent holder to enter into a standard license agreement** on terms consistent with established market practice, as well as to maintain good faith participation in pre-trial negotiations.
- The applicant is required to specify the **proposed terms** for the granting of a compulsory license, including the **anticipated scope of use** of the intellectual property, as well as the amount, procedure, and timeline for royalty payments.

确立获得强制许可的意愿

- 期望并要求强制许可申请人证明其已向专利权人正式提出要约，按照符合既定市场惯例的条款签订标准许可协议，并以诚信态度参与审前谈判。
- 要求申请人说明授予强制许可的拟定条款，包括知识产权的预期使用范围，以及使用费的金额、支付程序和时间表。

- The applicant must demonstrate **its readiness to manufacture and supply the product**, including the capability to produce it using methods that replicate the properties and qualities of the original. This must ensure that the clinical effect for the consumer is identical to that of the original product or substantially similar in all material parameters.
- The pivotal point is to prove that the Russian manufacturer possesses the necessary **technological infrastructure and raw material base** (specifically, GMP certifications and active pharmaceutical ingredient (API) registrations). The court must be assured that the license is not being granted 'in a vacuum,' but rather to a functionally operational producer capable of addressing the shortage within the shortest possible timeframe.

- 申请人必须证明其已准备好生产和供应产品，包括有能力使用能够复制原产品特性和质量的方法进行生产。这必须确保对消费者而言，临床效果与原产品相同或在所有重要参数上实质相似。
- 关键在于证明俄罗斯制造商拥有必要的**技术基础设施和原材料基础**（特别是GMP认证和原料药注册）。必须让法院确信，许可并非“空中楼阁”式地授予，而是授予一个能够在最短时间内解决短缺问题的、实际运营的生产商。

COMPULSORY LICENSING IS A 'SURGICAL INTERVENTION' RATHER THAN A SYSTEMIC PRACTICE

An excessively broad application of compulsory licensing without sufficient grounds risks undermining the reputation of the Russian jurisdiction, negatively impacting its investment attractiveness and discouraging the import of innovative products into the territory.

The position of the Constitutional Court of the Russian Federation in Ruling No. 13-P clearly emphasizes the necessity of maintaining a balance: a compulsory license must not serve as a tool for unfair competition.

强制许可是一种“外科手术式干预”，而非普遍适用的常规手段。

在没有充分理由的情况下过宽适用强制许可，可能会损害俄罗斯司法管辖区的声誉，对其投资吸引力产生负面影响，并阻碍创新产品进口到其境内。

俄罗斯联邦宪法法院在第**13-P**号裁定中的立场明确强调了保持平衡的必要性：强制许可绝不能成为不公平竞争的工具。

If a license applicant, seeking to produce a product with a consumer effect equivalent to the original, fails to disclose to the court—even within a closed-door **proceeding—genuine information regarding the specific product they intend to manufacture**, the resulting consequences fall within the scope of their own risks. Under certain circumstances, such conduct may be qualified **by the court as procedural bad faith**.

An application for a license **must not be driven by entrepreneurial adventurism, unjustified ambitions, or unrealistic plans**; furthermore, **it must not be predicated** on malicious intent—such as seeking to act solely to the detriment of the patent holder, for the purposes of 'patent trolling,' or with fraudulent intent.

On the **contrary, the existence of such a mechanism incentivizes global players to localize production and seek compromises on pricing**. This ultimately preserves patient access to innovations, but on equitable and fair terms.

如果寻求生产与原产品具有同等消费者效果的产品的许可申请人，未能向法院——即使在闭门程序中——披露其打算制造的具体产品的真实信息，则由此产生的后果由其自行承担风险。在某些情况下，此类行为可能被法院认定为程序上的不诚信。许可申请不得出于创业冒险主义、不正当的野心或不切实际的计划；此外，不得基于恶意——例如，行事仅为了损害专利权人利益、出于“专利流氓”目的或带有欺诈意图。

相反，此类机制的存在激励全球参与者本地化生产并寻求定价妥协。这最终能确保患者以公平合理的条款获得创新药物。

Constitutional Court of the Russian Federation :

“Patent ownership is not absolute and cannot be exercised to the detriment of constitutionally significant values most notably, the citizens' right to life and health protection. Access to such fundamental rights cannot be restricted solely by the commercial interests of the rights holder.”

俄罗斯联邦宪法法院:

“专利权并非绝对，其行使不得损害具有宪法重要性的价值观——尤其是公民的生命权和健康保护权。对此类基本权利的获取不能仅因权利人的商业利益而受到限制。”

Divisional applications. Case study.

Cases AstraZeneca vs. «Akrihin» (SIP-298/2025) and vs. KRKA (SIP-552/2022)

AstraZeneca has obtained seven core patents in the Russian Federation for the SGLT2 inhibitor dapagliflozin, the active pharmaceutical ingredient of Forxiga, indicated for the treatment of type 2 diabetes, heart failure, and chronic kidney disease.

分案申请。 案例研究。

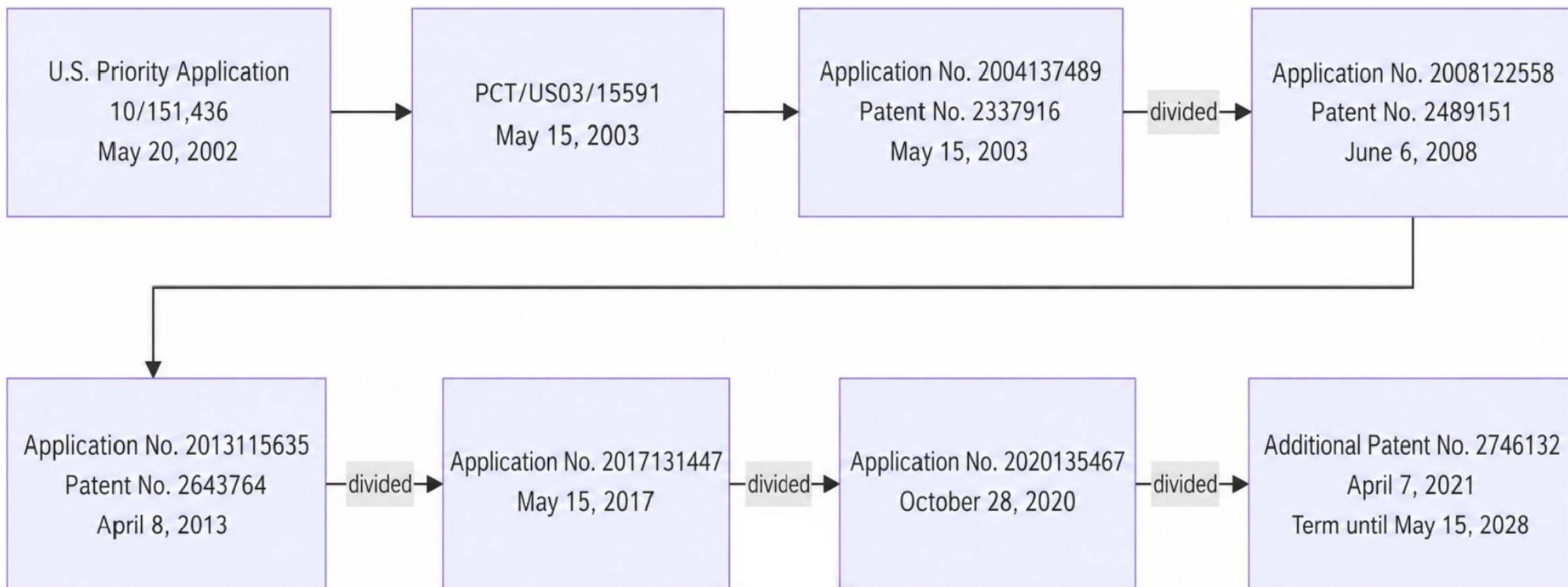
阿斯利康诉阿克希林公司案（SIP-298/2025）及诉KRKA公司案（SIP-552/2022）

阿斯利康已在俄罗斯联邦获得了关于SGLT2抑制剂达格列净的七项核心专利。达格列净是安达唐的活性药物成分，用于治疗2型糖尿病、心力衰竭和慢性肾病。



**The SEQUENCE of applications leading to
the issuance of RU Supplementary Patent
No. 2746132.**

**导致RU补充专利第2746132号授权的申
请序列。**



KEY PATENTS

➤ RU Patent No. 2262507 (term: until Oct 2, 2020) for a group of inventions (C-ARYL GLUCOSIDE SGLT2 INHIBITORS), wherein the formula for dapagliflozin is presented in Claim 16.

➤ RU Patent No. 2337916 (term: until May 15, 2023) for a group of inventions (C-ARYL GLUCOSIDE SGLT2 INHIBITORS AND METHOD OF USE), wherein the claims for dapagliflozin are presented in Claims 1-2, and Claim 3 discloses a pharmaceutical composition based thereon.

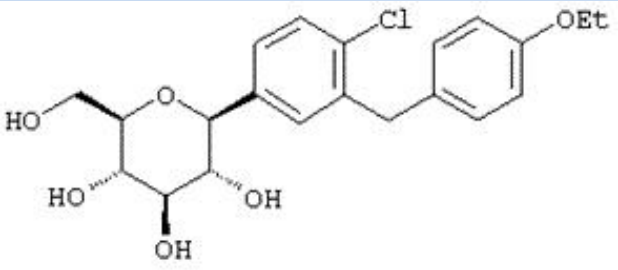
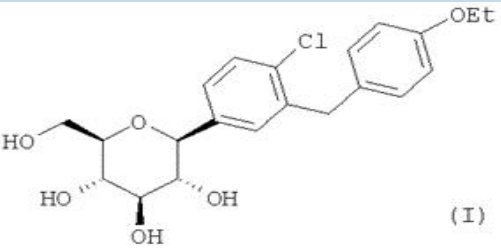
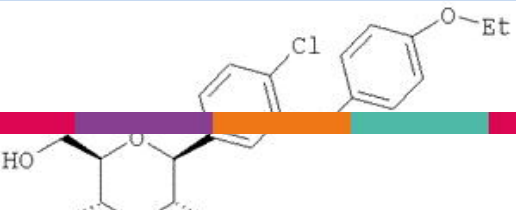
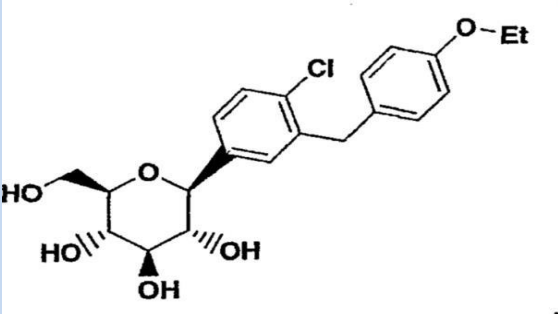
These patents effectively provided the core protection for the substance!

核心专利

RU专利号**2262507**（有效期：至**2020年10月2日**），涉及一组发明（**C-芳基葡萄糖苷SGLT2抑制剂**），其中第**16**项权利要求给出了达格列净的化学式。

RU专利号**2337916**（有效期：至**2023年5月15日**），涉及一组发明（**C-芳基葡萄糖苷SGLT2抑制剂及其使用方法**），其中第**1-2**项权利要求保护达格列净，第**3**项权利要求公开了基于其的药物组合物。

这些专利实质上为该化合物提供了核心保护！

RU Patent No. 2262507 C-ARYL GLUCOSIDE SGLT2 INHIBITORS RU专利号2262507 C-芳基葡萄糖苷SGLT2抑制剂	RU Patent No.2337916 «C-ARYL GLUCOSIDE SGLT2 INHIBITORS AND METHOD OF USE» RU专利号2337916 《C-芳基葡萄糖苷SGLT2抑制剂及其使用方法》	RU Supplementary Patent No. 2746132 «C-ARYL GLUCOSIDE SGLT2 INHIBITORS AND METHOD OF USE» RU补充专利第2746132号《C-芳基葡萄糖苷SGLT2抑制剂及其使用方法》
RU Application No. 2002109477, 02.10.2000 RU申请号2002109477, 申请日2000年10月2日	RU Application No. 2004137489, 15.05.2003 RU申请号2004137489, 申请日2003年5月15日	RU Application No. 2020135467, 28.10.2020 (Divisional of 2017131447, 07.09.2017) RU申请号2020135467, 申请日2020年10月28日 (分案自2017131447, 申请日2017年9月7日)
Expired on 03.10.2020 于2020年10月3日到期	Terminated prematurely on March 16, 2021, based on the patent holder's application 根据专利权人的申请于2021年3月16日提前终止	Extended from May 16, 2023, to May 15, 2028 有效期从2023年5月16日延长至2028年5月15日
1. The compound according to Claim 1, having the formula 1. 根据权利要求1所述的具有下式的化合物 	1. The compound having the structure or a pharmaceutically acceptable salt thereof. 1. 具有该结构的化合物或其药学上可接受的盐。  2. The compound according to Claim 1, having the structure 2. 根据权利要求1所述的具有该结构的化合物 	A pharmaceutical composition having an SGLT2 inhibitory effect, comprising a compound of the formula and a pharmaceutically acceptable carrier. 一种具有SGLT2抑制作用的药物组合物, 包含具有下式的化合物和药学上可接受的载体。 

THE PATENT PORTFOLIO OF ASTRAZENECA

- **1. RU Patent No. 2262507** (Application No. 2002109477, filed Oct 2, 2000): C-Aryl Glucoside SGLT2 Inhibitors. Expired on Oct 3, 2020, however, the claims are included in subsequent protection documents.
- **2. RU Patent No. 2337916** (Application No. 2004137489, May 15, 2003): C-ARYL GLUCOSIDE SGLT2 INHIBITORS AND METHOD OF USE. Terminated prematurely on March 16, 2021, based on the patent holder's application. →
- **3. RU Supplementary Patent No. 2489151** (Application No. 2008122558, June 6, 2008): Pharmaceutical combination containing an SGLT2 inhibitor. Divisional of: 2004137489, May 15, 2003. Extended from May 16, 2023, to May 15, 2028. →
- **4. RU Patent No. 2643764** (Application No. 2013115635, April 8, 2013): PREPARATION AND USE OF AN SGLT2 INHIBITOR. Divisional of: 2008122558, June 6, 2008. Expired on May 16, 2023. →
- **5. RU Application No. 2017131447**, September 7, 2017: METHODS FOR THE PREPARATION AND USE OF AN SGLT2 INHIBITOR. Initial application from which this application was divided: 2013115635, April 8, 2013. Refusal to grant a patent on September 7, 2023. →

阿斯利康的专利组合

- 1. RU专利号2262507** (申请号2002109477, 申请日2000年10月2日): C-芳基葡萄糖苷SGLT2抑制剂。于2020年10月3日到期, 但其权利要求包含在后续的保护文件中。
- 2. RU专利号2337916** (申请号2004137489, 申请日2003年5月15日): C-芳基葡萄糖苷SGLT2抑制剂及其使用方法。根据专利权人的申请于2021年3月16日提前终止。
- 3. RU补充专利第2489151号** (申请号2008122558, 申请日2008年6月6日): 含有SGLT2抑制剂的药物组合。分案自: 2004137489, 申请日2003年5月15日。有效期从2023年5月16日延长至2028年5月15日。
- 4. RU专利号2643764** (申请号2013115635, 申请日2013年4月8日): SGLT2抑制剂的制备和用途。分案自: 2008122558, 申请日2008年6月6日。于2023年5月16日到期。
- 5. RU申请号2017131447**, 申请日2017年9月7日: SGLT2抑制剂的制备和用途方法。本申请分案自原始申请: 2013115635, 申请日2013年4月8日。于2023年9月7日被驳回。

6. RU Supplementary Patent No. 2746132 (Application No. **2020135467**, **October 28, 2020**): C-ARYL GLUCOSIDE SGLT2 INHIBITORS AND METHOD OF USE. Divisional of: **2017131447**, **September 7, 2017**. Extended from May 16, 2023, to May 15, 2028.

➤ **7. RU Supplementary Patent No. 2800510** (Application No. **2020135467**, **October 28, 2020**). Divisional of: **2017131447**, **September 7, 2017**. Invalid since August 9, 2025. Annulled as of the application filing date.

6. RU补充专利第2746132号（申请号**2020135467**，申请日**2020年10月28日**）：C-芳基葡萄糖苷SGLT2抑制剂及其使用方法。分案自：**2017131447**，申请日**2017年9月7日**。有效期从**2023年5月16日**延长至**2028年5月15日**。

7. RU补充专利第2800510号（申请号**2020135467**，申请日**2020年10月28日**）。分案自：**2017131447**，申请日**2017年9月7日**。自**2025年8月9日**起无效。自申请日起被宣告无效。

On April 24, 2023, Rospatent upheld an objection filed on June 28, 2022, and declared RU Patent No. 2746132 partially invalid. A patent for the invention was issued with the claims presented on March 9, 2023 (see RU Patent No. 2800510).

On September 28, 2023, Rospatent upheld an objection filed by Akrikhin on November 17, 2022, and declared RU Supplementary Patent No. 2746132 partially invalid. A new supplementary patent was issued with the claims presented on September 25, 2023 (see RU Patent No. 2746132).

IP Court (1-st Instance and Cassation) agreed with Russian PTO on these invalidation decisions.

2023年4月24日，俄罗斯联邦知识产权局支持了2022年6月28日提出的异议，宣告RU专利号2746132部分无效。根据2023年3月9日提交的权利要求，重新颁发了该发明的专利（见RU专利号2800510）。

2023年9月28日，俄罗斯联邦知识产权局支持了阿克希林于2022年11月17日提出的异议，宣告RU补充专利第2746132号部分无效。根据2023年9月25日提交的权利要求，重新颁发了新的补充专利（见RU专利号2746132）。

知识产权法院(第一审和最高判决)同意俄罗斯PTO对这些无效宣告的决定。

Supreme Court decision of June 17, 2024 on the Case № SIP-552/2022 AstraZeneca vs KRKA d.d. Novo mesto

The Supreme Court cancelled Russian PTO decision, IP Court and IP Court Cassation decisions **ruling that the "cascading division" of applications (where one application is filed based on another while maintaining the priority date of the first) does not violate the law.**

This decision effectively restored the patent protection for RU Patent No. 2746132 dapagliflozin until May 2028.

最高法院2024年6月17日关于案件号SIP-552/2022 阿斯利康诉KRKA公司新梅斯托的裁决

最高法院取消了俄罗斯PTO裁决，知识产权法院和知识产权法院撤销判决，裁定申请的"级联划分"（其中一个申请是基于另一个申请提出的，同时保持第一个

这一裁决实质上恢复了对RU专利号2746132达格列净的专利保护，直至2028年5月。

What to do to manufacture dapagliflozin and don't infringe patent valid until May 2028?

如何制造dapagliflozin并且在5月2028之前不侵犯专利有效？

Recognition of the right to use expired patents

Case No. SIP-298/2025, the Presidium of the Intellectual Property Court (IPC) has issued a final confirmation of Akrikhin's right to manufacture the generic drug Fordiglif.

The IPC ordered the following:

➤ Recognized the right to use the formulas: The Court confirmed that Akrikhin may lawfully use the inventions under Patents No. 2262507 (Claim 16 — active ingredient) and No. 2337916 (Claim 3 — pharmaceutical composition).

➤ Established the transition to the public interests: The IPC stated that since the terms of these AstraZeneca patents have expired, the technical solutions have become available for free use without the consent of the right holder or the payment of royalties.

承认使用已过期专利的权利

在案件号SIP-298/2025中，知识产权法院主席团最终确认了阿克希林生产仿制药Fordiglif的权利。

知识产权法院命令如下：

承认使用化学式的权利： 法院确认阿克希林可以合法使用专利号2262507（化学式16——活性成分）和专利号2337916（化学式3——药物组合物）项下的发明。

确认已进入公有领域： 知识产权法院指出，由于阿斯利康这些专利的期限已届满，其技术解决方案已成为可供自由使用，无需权利人同意或支付使用费。

...

- Curbed the abuse of right: The Court concluded that **AstraZeneca's acquisition of supplementary patent No. 2746132 for the same composition (via the "cascading divisional" application mechanism) was an attempt to bypass the law and artificially extend its market monopoly.**
- Prohibited defamation: **The Court ordered AstraZeneca to refrain from sending letters that discredit the activities of Akrikhin or the drug Fordiglif, and to cease creating obstacles to its entry into civil circulation.**

...

遏制权利滥用：法院认定，阿斯利康通过“级联分案”申请机制为同一组合物获得补充专利第2746132号，是试图规避法律并人为延长其市场垄断。

禁止诋毁：法院责令阿斯利康不得发送贬低阿克希林公司活动或Fordiglif药物的信函，并停止为其进入民事流通设置障碍。

On April 20, 2026, AstraZeneca filed a cassation appeal with the Supreme Court of the Russian Federation.

Supreme Court of the Russian Federation rejected AstraZeneca's cassation appeal.

2026年4月20日，阿斯利康向俄罗斯联邦最高法院提起上诉。

俄罗斯联邦最高法院驳回了阿斯利康公司的最高法院再审申请。

Legal Significance of the Case SIP-298/2025

➤ Case SIP-298/2025 has become one of the most discussed in Russian pharmaceutical patent law. The court did not invalidate the patent but **restricted its enforcement through the doctrine of abuse of right, effectively permitting the use of the invention despite the active status of RU Patent No. 2746132.**

➤ This case is being described as a landmark precedent, as **it addresses bypassing patent protection to ensure public access to vital medicines and establishes new legal approaches to "evergreen" patent disputes** and the use of originator patents.

➤ This is a highly atypical approach for the Russian patent system!

SIP-298/2025案件的法律意义

- SIP-298/2025案件已成为俄罗斯制药专利法领域讨论最多的案件之一。法院并未宣告专利无效，而是通过权利滥用原则限制其执行，实质上允许了在RU专利号2746132仍然有效的情况下使用该发明。

- 该案被视为一个里程碑式的先例，因为它涉及为了确保公众获得重要药物而在专利保护仍然有效的情况下合法使用其发明的问题，并为处理“常青”专利纠纷和原研药专利的使用确立了新的法律方法。

- 对于俄罗斯专利体系而言，这是一种极不寻常的方法！

THANK YOU!
ANY QUESTIONS?

感谢聆听！
如有疑问，敬请垂询
！

