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# Frontier Analysis of Innovative Drug Empagliflozin

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**Abstract:** Empagliflozin is a sodium-glucose co-transporter 2 (SGLT-2) inhibitor used in the treatment of type 2 diabetes mellitus (T2DM). Its advantages lie not only in lowering blood glucose but also in reducing the risk of cardiovascular death. A hallmark of innovative drugs is their associated patent protection. This paper presents a statistical and analytical overview of invention patents related to empagliflozin in China, covering aspects such as key applicants, applicant nationalities, application trends over the past 20 years, technological field distribution, and patent tagging. The goal is to understand trends, hotspots, and focal points in the technological development of innovative drugs related to empagliflozin. Special attention is given to the patent applications of Boehringer Ingelheim International GmbH, a representative applicant in this field. Since patents represent the frontline layout of innovative drugs, this frontier analysis of empagliflozin provides a valuable reference for pharmaceutical research and development.

**Keywords:** Empagliflozin; SGLT2 inhibitor; Type 2 diabetes mellitus; Patent

## Introduction

Empagliflozin is a sodium-glucose co-transporter 2 (SGLT-2) inhibitor used in the treatment of type 2 diabetes mellitus (T2DM), co-developed by Eli Lilly and Boehringer Ingelheim [1]. It was approved by the U.S. Food and Drug Administration (FDA) on August 1, 2014, becoming the third oral SGLT-2 inhibitor approved in the U.S., following canagliflozin and dapagliflozin. By inhibiting SGLT-2 expression in the kidneys, empagliflozin reduces renal glucose reabsorption, thereby lowering plasma glucose levels in adults with T2DM [2]. Empagliflozin is distinguished not only by its glucose-lowering effects but also by its ability to reduce cardiovascular mortality. It is the first SGLT-2 inhibitor approved by the FDA for reducing the risk of cardiovascular death in adult T2DM patients with established cardiovascular disease. Due to the serious complications associated with diabetes, combination therapy is often necessary. Empagliflozin offers considerable advantages in this context. For instance, in a study on the effects of metformin combined with empagliflozin in obese patients with T2DM, Li Tingting reported the combination to be both safe and effective, promoting glyco-lipid metabolism and weight control in patients [3]. In cross-drug comparisons, empagliflozin is recognized for its therapeutic efficacy and low rate of adverse reactions.

For example, Niu Huaifa, in the article *Comparison of the Effects of Empagliflozin, Liraglutide, and Metformin in the Treatment of Patients with New-onset*

*Type 2 Diabetes and Non-alcoholic Fatty Liver Disease,* pointed out that both empagliflozin and liraglutide can reduce blood glucose levels, inflammatory markers, D-dimer levels, and liver function indicators in patients newly diagnosed with type 2 diabetes mellitus (T2DM) combined with non-alcoholic fatty liver disease (NAFLD). Their effectiveness was superior to that of metformin. The therapeutic effects of empagliflozin and liraglutide were comparable, but the incidence of adverse reactions with empagliflozin was lower than that of both liraglutide and metformin, while the rates of adverse reactions for liraglutide and metformin were similar.

## 1. Source of Patent Data

This study employed publicly available online search tools as the primary means for patent retrieval and analysis, supplemented with data validation using the Himmpat patent database. The search strategy applied was: (" 恩 格 列 净 " OR " 依 帕 列 净 " OR "Empagliflozin") and (" 糖 尿 病 " OR "diabetes" OR "glycuresis"). In addition, for compound-specific searches, the CAS registry number of empagliflozin (864070-44-0) was used to conduct a query in the STN database. Using the above strategies, a total of 666 invention patent documents related to empagliflozin in China were retrieved. The patent search was completed as of March 20, 2025.

## 2. Analysis of Patent Application Trends

### 2.1 Analysis of the Number of Empagliflozin Patent Applications in China

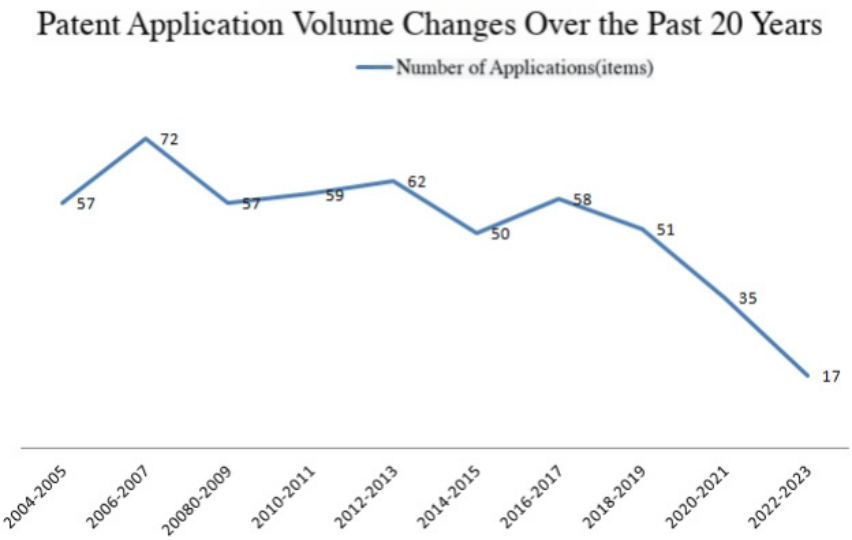


**Figure 1.** Application Volume Trend of Empagliflozin Patents Over the Past 20 Years

Given the extended 20-year span of the dataset, annual statistics would result in an overly dense chart. Therefore, starting from 2004, the sum of applications over every two-year period was used as a single data point. As shown in **Figure 1,** the peak occurred during 2006–2007, with a total of 72 applications. Between 2008 and 2017, the number of applications remained relatively stable, fluctuating between 50 and 62 applications per two-year period. After 2019, a decline in application volume is observed.This trend reflects the development cycle of empagliflozin-related patents. Beginning with the compound patent filed in 2004, a substantial number of follow-up patents were filed concerning synthesis methods, crystal forms, and structural modifications. From the initial compound patent application in 2004 to the drug's market approval in 2014, it took more than a decade. Although the drug was launched in 2014, the number of patent applications continued to rise steadily over the next five years, only beginning to decline around 2019. This trend reflects not only follow-up applications from the original innovator but also a wave of subsequent filings by other pharmaceutical companies. The changes in application volume indicate that major companies have placed considerable emphasis on patent protection for this drug.

### 2.2 Analysis of Major Applicants for Empagliflozin Patents

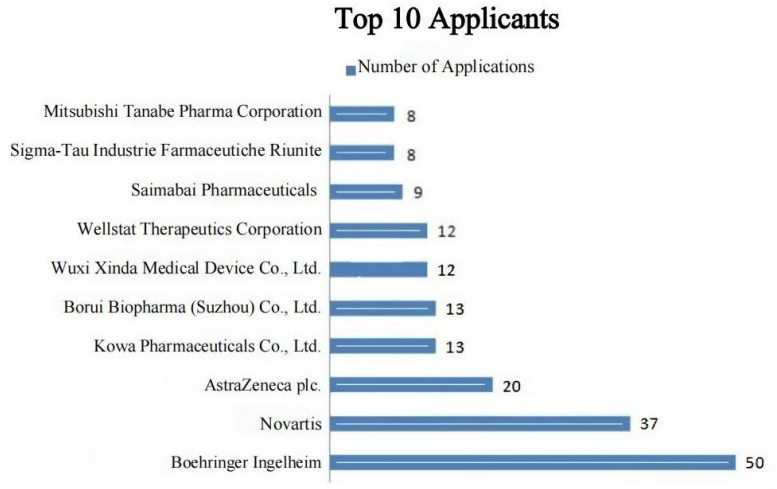


**Figure 2.** Top 10 Applicants for Empagliflozin Patents

As shown in **Figure 2,** among the top 10 applicants for empagliflozin–related patents, eight are foreign enterprises, while only two are domestic Chinese companies. Boehringer Ingelheim International GmbH ranks first with 50 applications, followed by Novartis with 37, and AstraZeneca in third with 20. Kowa Co., Ltd. and Borui Biomedical Technology (Suzhou) Co., Ltd. are tied for fourth place, each with 13 applications.This distribution demonstrates a clear dominance of foreign companies in the patent landscape for empagliflozin. The top three applicants are all multinational pharmaceutical firms, indicating their high level of engagement and concentrated patent activity. It reflects the foreign–led nature of empagliflozin's intellectual property strategy within China.

## 3. Top 10 Countries of Origin for Empagliflozin Patent Applicants in China

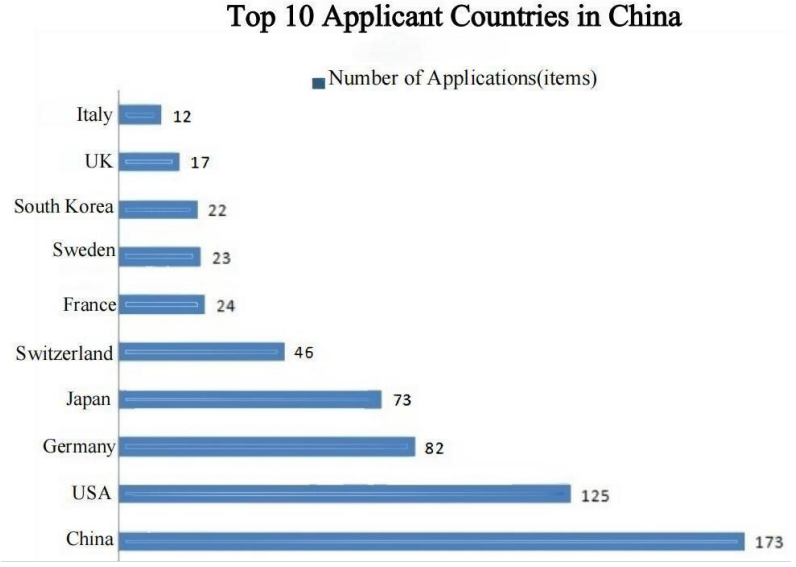


**Figure 3**. Top 10 Countries of Origin for Empagliflozin Patent Applicants in China

As shown in **Figure 3**, the top 10 countries of origin for empagliflozin patent applicants in China are predominantly leading pharmaceutical nations. The top seven—China, the United States, Germany, Japan, Switzerland, France, and Sweden—are all countries with globally recognized pharmaceutical industries. Notably, "China" includes both domestic applicants and foreign entities registered in China.Most of the applications from these countries were submitted via the Patent Cooperation Treaty (PCT) route, although

some also entered China through the Paris Convention route. The strong presence of these countries in the Chinese patent system highlights the strategic importance of the Chinese market, given its large diabetic population and high demand for anti-diabetic therapies like empagliflozin. This trend underscores the commitment of foreign pharmaceutical firms to securing intellectual property rights in China.

## 4. Top 10 Countries and Regions for Empagliflozin Patent Families

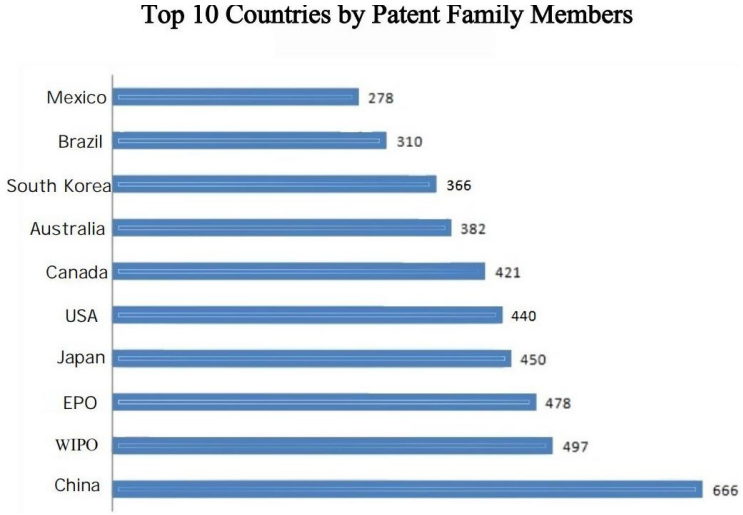


**Figure 4**. Top 10 Countries and Regions for Empagliflozin Patent Families

As shown in **Figure 4**, the top 10 countries and regions in terms of empagliflozin patent family filings are: China, WIPO (World Intellectual Property Organization), the European Union, Japan, the United States, Canada, Australia, South Korea, Brazil, and Mexico. China ranks first with 666 patent family members, followed by WIPO, the EU, and Japan, with counts ranging from 497 to 421, indicating relatively close volumes among them.The even distribution of patent filings across these jurisdictions suggests a globally balanced patent strategy by the applicants. These countries and regions represent the core markets and regulatory environments for innovative pharmaceuticals, further demonstrating their importance in the global development and commercialization of empagliflozin.

## 5. Technical Field Distribution of Empagliflozin Invention Patents

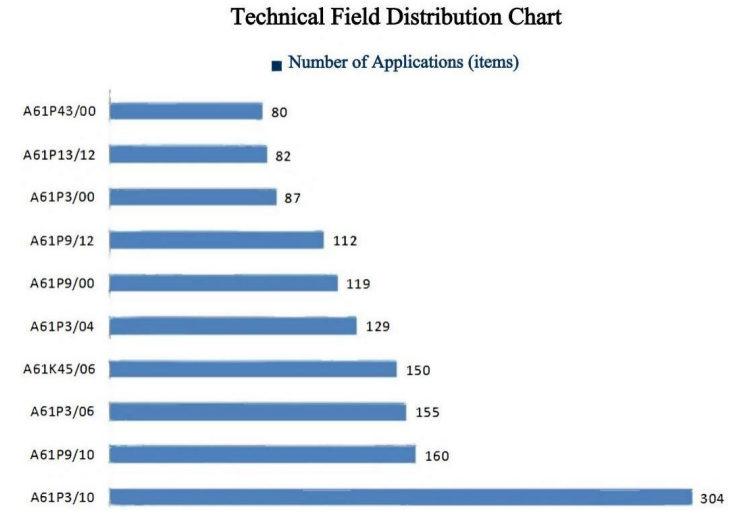


**Figure 5.** Technical Field Distribution of Empagliflozin Patents

As shown in **Figure 5,** the invention patent applications for empagliflozin are primarily concentrated in therapeutic use categories under IPC classification A61P. Specifically, A61P3/10 refers to drugs for treating hyperglycemia, A61P9/10 to drugs for treating localized ischemia or atherosclerotic diseases, A61P3/06 to antihyperlipidemic agents, A61P3/04 to anti-obesity drugs, A61P9/00 to cardiovascular drugs, and A61P9/12 to antihypertensive agents. This indicates that the primary therapeutic applications of empagliflozin patents focus on diabetes, cardiovascular and hypertensive diseases, and obesity, all of which are common chronic conditions with large global patient populations. This medical demand forms the basis for empagliflozin's substantial market performance, including a global sales revenue of USD 10.612 billion in 2023 and a 29.3% year-on-year growth rate, and also reflects the concentration of patent activity within these major therapeutic fields.

## 6. Tag Analysis of Empagliflozin Invention Patents

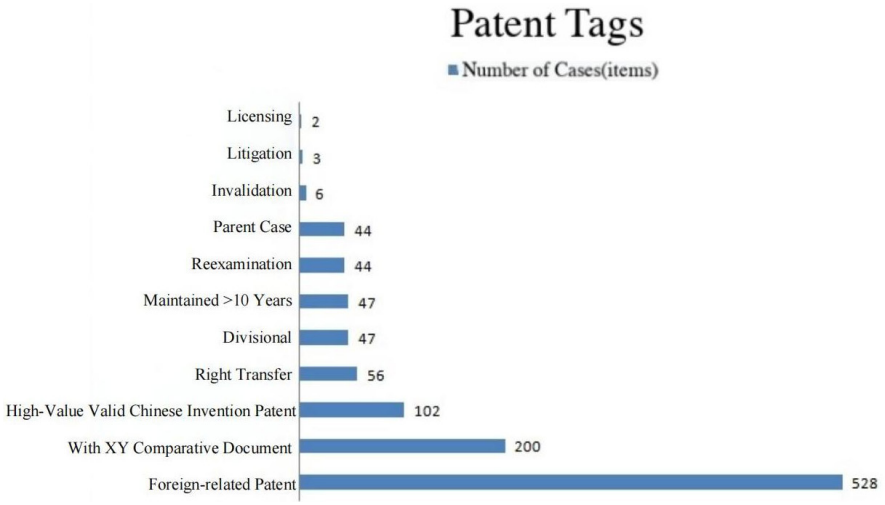


**Figure 6.** Tag Distribution of Empagliflozin Patents

As shown in **Figure 6,** among the 666 empagliflozin-related invention patents filed in China, 528 (79.3%) are foreign-related patents, 102 are high-value valid Chinese invention patents, 56 have undergone rights transfers, 47 are divisional applications, 47 have been maintained for more than 10 years, 3 are involved in litigation, and 2 have been licensed. These indicators reflect the high practical and commercial value of most empagliflozin invention patents, as evidenced by their inclusion in international patent families, transfer of rights, divisional filings, legal disputes, licensing, and long-term maintenance. The maintenance of a patent beyond 10 years, which involves steep increases in annuity fees, and the high costs associated with litigation and reexamination suggest that the applicants or patent holders are willing to make significant financial investments in order to preserve and enforce these high-value patents for greater economic gain. Divisional applications, in particular, demonstrate a strong desire for patent grant or for securing more refined and comprehensive protection, underscoring the strategic importance of these patents. Notably, 200 of the 666 patents include XY comparison documents, indicating that nearly one-third of the applications were found to lack novelty or inventive step. Combined with the technical field distribution shown in Figure 5, which reveals a heavy focus on therapeutic use patents, it becomes evident that there is significant redundancy among later-stage filings, particularly in the areas of diabetes and cardiovascular diseases. Therefore, future patent exploration and development may benefit from expanding into other indications, formulation innovations, compound modifications, or new crystalline forms of empagliflozin.

## 7. Analysis of the Empagliflozin Patent Portfolio of Boehringer Ingelheim International GmbH in China

### 7.1 Technical Theme Distribution of Patents Filed by Boehringer Ingelheim International GmbH

As the original developer of empagliflozin, Boehringer Ingelheim International GmbH has demonstrated a strong awareness of patent protection for empagliflozin in China, with a total of 50 related patents. The distribution of technical themes within its patent portfolio is as follows:

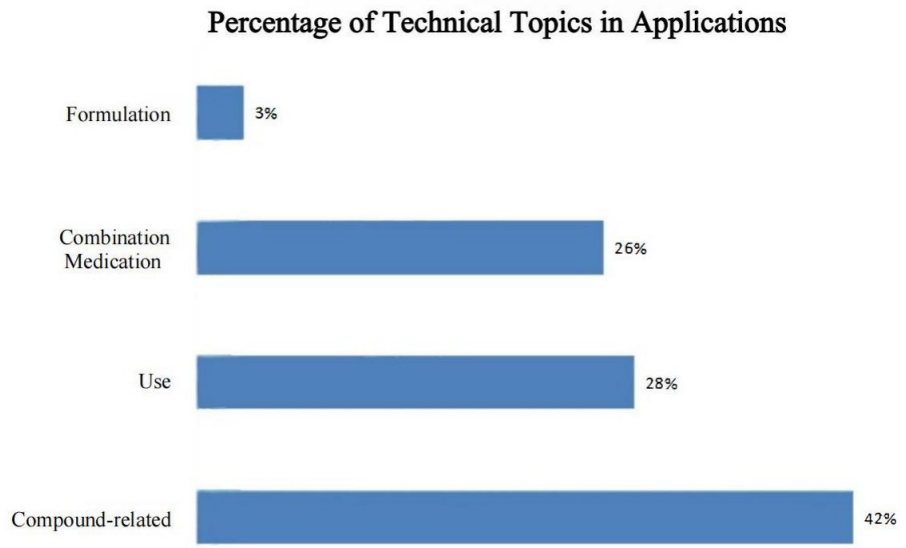


**Figure 7.** Percentage Distribution of Technical Themes in Empagliflozin Applications

As shown in **Figure 7,** apart from the initial compound patents, use patents account for a relatively large proportion, mainly involving the treatment of diabetes and cardiovascular diseases, followed by patents on combination therapies, formulations, and preparation methods. In terms of compound patents, the applications mainly relate to structurally modified compounds with high innovation. This approach not only enables the continuous development of more effective structural derivatives, but also helps extend the patent protection period. Moreover, it builds a tightly woven patent protection network that makes it difficult for competitors to gain a foothold, thus securing long–term monopoly benefits in the Chinese market. The company's strategy of continuous modification of structures or crystalline forms, along with the layout of new use patents such as combination therapies, is also worth learning from for domestic pharmaceutical companies.

### 7.2 Key Patent Analysis of Boehringer Ingelheim International GmbH

In terms of compound patents, Boehringer Ingelheim filed a PCT international application for empagliflozin in 2005, which serves as the foundational patent for the drug. The publication number is WO2005092877A1, and its Chinese national application number is CN200580006944, which was later followed by four divisional applications. This patent is based on a glucoside–phenyl–phenyl core structure written using a Markush formula with broad substitution ranges, thereby covering a wide range of compounds sharing the same core glycoside structure and forming substantial patent barriers for subsequent entrants.

Regarding combination therapy, WO2008055940A2 claims protection for the use of empagliflozin in combination with metformin; however, as the original compound patent CN200580006944.9 had already disclosed such a combination, the Chinese application CN200780041878.8 for WO2008055940A2 was ultimately rejected.

## Conclusion

One of the core features of innovative drugs is their association with patent protection, which represents the most forward–looking phase of pharmaceutical development. From the preceding analysis of empagliflozin's patent landscape, it is clear that the innovation surrounding this drug spans a broad array of technical domains. The primary applicants have filed patents covering the compound and its derivatives, structural modifications, preparation methods, combination therapies, medical uses, crystalline forms,

and formulations. With the core compound patent of empagliflozin nearing expiration, formulation and new dosage form patents currently represent a relatively weak segment of the portfolio. Given that diabetes patients require long-term medication, there is substantial demand for more comfortable and convenient modes of administration. Therefore, innovation in new dosage forms of empagliflozin presents a promising avenue. Moreover, the field of pharmaceutical formulations includes several subcategories—such as prescription patents, process patents, and dosage form patents—with technologies like liposomes, microspheres, nanotechnology, sustained-release and controlled-release systems, and long-acting formulations all representing promising directions for further exploration. Pharmaceutical companies would benefit from early-stage research and patent deployment in these underdeveloped areas of empagliflozin to gain a strategic edge in the market and develop better medicines that serve the public.

## References

[1] Niu Huaifa. Comparison of the Efficacy of Empagliflozin, Liraglutide, and Metformin in Treating Newly Diagnosed Type 2 Diabetes Patients with Non-Alcoholic Fatty Liver Disease [J]. China Practical Medicine, 2023, 35(17): 152–155.

[2] Lai Shuyan. Polymorphism Study of Hypoglycemic Drug Empagliflozin, Master's Thesis, Zhejiang Sci-Tech University, 2020, p.8.

[3] Li Tingting. Study on the Effect of Metformin Combined with Empagliflozin on Glucose and Lipid Metabolism in Obese Patients with Type 2 Diabetes [J]. Diabetes New World, 2024(4): 96–99.