

Mapping the development of fibrates based on a technology and market analysis

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碩士學位論文

基於專利及市場分析的
治療高甘油三酯血症貝特類藥物
發展現狀研究

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Abstract

Background: Relation between hypertriglyceridemia and cardiovascular diseases are proved recently. Fibrates is the most effective drug in lowering triglyceride clinically. However, little is known about its current development.

Objective: Using cross-database patent analysis and products as well as sales value analysis, to map the development of fibrates.

Method: Patents data were collected in March 2013 from the United States Patent and Trademark Office (USPTO), the European Patent Office (EPO) and the China Intellectual Property Right Net (CNIPR) to represent global patent activities. Patent distribution was analysed by chemical name, year, country, assignee as well as assignee sector, technological type and International Patent Classification (IPC) code. A technology roadmap aiming to identify the technology evolution pathway was drawn afterwards based on information extracted from the patents. Permitted products of fibrates with different specifications were retrieved from China Food and Drug Administration of China (CFDA) and the U. S. Food and Drug Administration (FDA). Global sales of fibrates were searched from IMS World Review 2010, sales growth from 2008 to 2012 was searched from MENET 2.0.

Result: Most of the patents are fenofibrate preparation and fibrates combination patents. Patents for new monomers, derivatives and new application of old fibrates emerged recently. Differences exist between fibrates products permitted by FDA and CFDA, but lack of delayed release fibrates is same. Fibrates is the second top-selling drug in therapeutic category of lipid regulation and anti-atherosclerosis drug. Most of the expenditure were in the US, Europe and Japan. Growth rate of 2011-2012 in China was 17%. Fenofibrate had the highest sales, sales of its brand name drug was higher than that of generic. Bezafibrate had the highest growth rate, sales of its brand name drug was lower than that of generic. Sales of gemfibrozil kept declining recent years.

Conclusion: Fibrates technology was led by Abbott, Ethypharm and Skyepharma. Fenofibrate preparation and fibrates combination were two core technologies. Fibrates market in developed countries was matured, while market in developing countries was in a growing stage. Commercialization of delayed or control release bezafibrate and fenofibric acid are the short-term market goals of fibrates. Preparation and combination, as well as patents of preparation and combination, influenced fibrates market performance a lot. New monomers or derivatives of fibrates, better drug delivery system and new application of old fibrates are long-term tendency of fibrates.

Key words

Fibrates, technology, market, development, patent, product, sales



摘要

背景：隨著高甘油三脂血癥危害性逐漸被發現，貝特類藥物作為當下最有效的降甘油三酯藥，其技術發展情況及市場情況並不知道。

目的：通過跨數據庫授權專利分析以及產品和銷售情況分析，描述貝特類藥物的發展現狀。

方法：利用美國，歐洲和中國專利局，檢索貝特類藥物授權專利以代表其技術的國際發展情況。對貝特類授權專利進行申請年、地域、受讓方、技術類型等分佈分析，隨後描繪貝特類藥物發展技術路線圖。利用美國食品藥品監督管理局以及中國食品藥品監督管理局，檢索在兩國批准上市的不同規格貝特類產品，進行產品分析。利用IMS World Review數據庫檢索貝特類藥物的國際銷售總額及市場分佈情況，利用米內數據庫檢索貝特類藥物的五年銷售變動情況，進行市場分析。

結果：貝特類藥物專利以非諾貝特的合用專利以及貝特類藥物與其他藥物合用的專利最多。專利總數的增長速率開始放緩，但製劑類專利數量仍在增長。新單體或衍生物以及老藥物新應用的專利開始出現。美國及中國獲批貝特產品的數量和品種上存在較大差異，但緩控釋劑型的缺稀情況相同。在降脂和抗動脈粥樣硬化治療領域中，貝特類藥物的銷售額僅次於他汀類藥物，美國、歐洲、日本等國的銷售額最高。2011-2012年，貝特類藥物在中國的銷售增長率為17%。非諾貝特的銷售額最高，其商標藥銷售高於仿製藥；苯扎貝特的銷售增長最快，其商標藥銷售低於仿製藥。吉非貝齊銷售額逐年下降。

結論：貝特類藥物技術集中于企業，由美國雅培，法國Ethypharm以及英國Skyepharma引領。技術熱點集中在非諾貝特製劑以及貝特類藥物與其它藥物合用上。貝特類藥物市場主要在歐美發達國家，發展中國家市場處於成長階段，隨著高甘油三酯血癥發病率增高以及危害性逐漸被認知，貝特類藥物具有不容小覷的市場潛力。苯扎貝特的緩控釋給藥以及非諾貝酸的普及是未來貝特類藥物的短期市場目標。由於貝特類藥物的特殊性質，製劑和合用技術及專利對其市場表現的影響更大。新單體或衍生物以及優良給藥系統的開發，老貝特新用途的開發是其未來的發展趨勢。

關鍵字：貝特，技術，市場，發展現狀，專利，產品，銷售

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Contents

Tables	iii
Figures.....	iv
List of Abbreviations	v
Chapter 1 Introduction.....	1
1.1 Hypertriglyceridemia	1
1.2 Fibrates.....	2
1.3 Aim of this study.....	2
Chapter 2 Methodology	4
2.1 Technology analysis by patents	4
2.1.1 Selection of databases	4
2.1.2 Retrieval criteria.....	4
2.1.3 Data analysis	4
2.2 Market analysis	5
2.2.1 Permitted fibrates	5
2.2.2 Sales value	5
Chapter 3 Technology of fibrates	6
3.1 Patent distribution by nation	7
3.2 Patent distribution by assignees	9
3.3 Patent distribution by technological type.....	11
3.4 Patent distribution by IPC code	13
3.5 Technology roadmap of fibrates	13
Chapter 4 Market analysis.....	16
4.1 Permitted fibrates	16
4.1.1 Fibrates permitted by FDA	16
4.1.2 Fibrates permitted by CFDA.....	16
4.2 Sales value of fibrates	17
4.2.1 Global sales value of fibrates	17
4.2.2 Chinese sales value of fibrates	18
Chapter 5 Discussion	22
5.1 Technology development of fibrates.....	22

5.1.1 Overall trend of fibrates	22
5.1.2 Core technology of fibrates.....	23
5.1.3 Evolution pathway of fibrates	23
5.2 Market conditions of fibrates	25
5.2.1 Products of fibrates	25
5.2.2 Sales of fibrates.....	25
5.3 Implication for China.....	26
5.4 Innovation of this study	27
5.5 Limitations and future research.....	27
Chapter 6 Conclusion	28
Reference	29
Publications	34



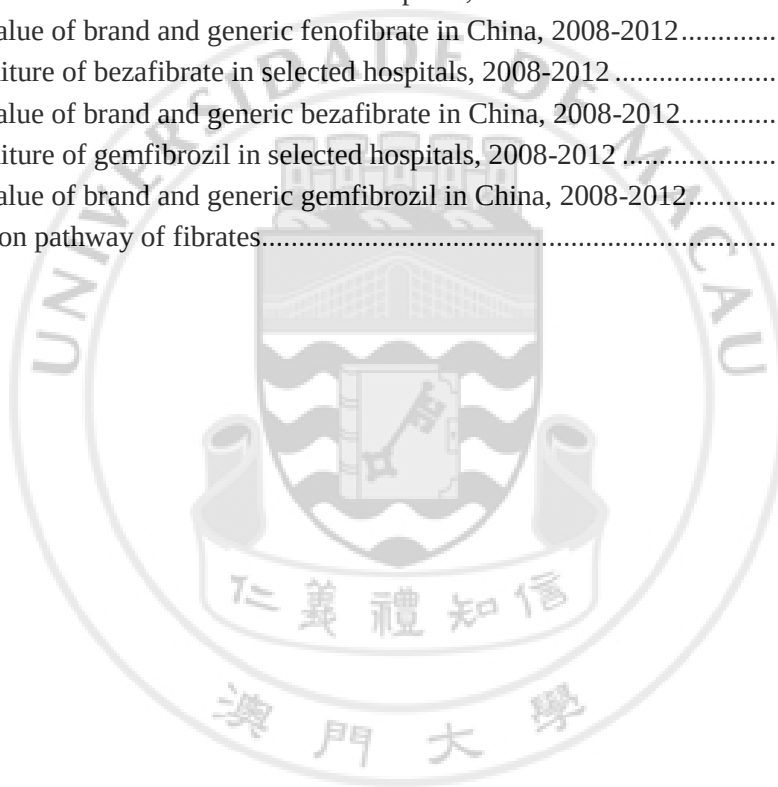
Tables

Table 1. 1 Diagnostic criteria of hypertriglyceridemia by ENDO	1
Table 3. 1 Result of patent collection in different patent offices	6
Table 3. 2 Distribution of fibrates patent by assignee sector at USPTO, EPO and CNIPR.....	10
Table 3. 3 Analysis of the main assignees in different patent offices.....	11
Table 3. 4 Distribution of fibrates patent by technological type at USPTO, EPO and CNIPR	12
Table 4. 1 Fibrates permitted by FDA	16
Table 4. 2 Fibrates permitted by CFDA.....	17



Figures

Figure 3. 1 Number of authorised fibrates patents at three patent offices by year of application....	7
Figure 3. 2 Distribution of patents in different market	8
Figure 3. 3 Fibrates patent flows between the US, Europe and China.....	8
Figure 3. 4 Distribution of different types of assignee at USPTO, EPO and CNIPR	9
Figure 3. 5 Cumulative graphs of different technological types by year	12
Figure 3. 6 Distribution of IPC codes at different patent offices	13
Figure 3. 7 Technology roadmap of fibrates.....	15
Figure 4. 1 Sales value of fibrates by countries, 2009 (million, US dollar).....	17
Figure 4. 2 Expenditure of fenofibrate in selected hospitals, 2008-2012	18
Figure 4. 3 Sales value of brand and generic fenofibrate in China, 2008-2012.....	19
Figure 4. 4 Expenditure of bezafibrate in selected hospitals, 2008-2012	20
Figure 4. 5 Sales value of brand and generic bezafibrate in China, 2008-2012.....	20
Figure 4. 6 Expenditure of gemfibrozil in selected hospitals, 2008-2012	21
Figure 4. 7 Sales value of brand and generic gemfibrozil in China, 2008-2012.....	21
Figure 5. 1 Evolution pathway of fibrates.....	23



List of Abbreviations



CFDA	China Food and Drug Administration of China
CHD	coronary heart disease
CNIPR	the China Intellectual Property Right Net
CVD	cardiovascular diseases
ENDO	the Endocrine Society
EPO	the European Patent Office
FDA	U. S. Food and Drug Administration
HDL-C	high-density lipoprotein-cholesterol
HTG	Hypertriglyceridemia
IPC	International Patent Classification
LDL-C	low-density lipoprotein cholesterol
PPAR α	peroxisome proliferator-activated receptor-alpha
TG	triglyceride
USPTO	the United States Patent and Trademark Office