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# Pharmaceutical patent infringement litigation warning indicator system

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**ABSTRACT**

*The patent infringement litigation warning models and early warning indicator system for pharmaceutical companies are established. A combination of qualitative and quantitative methods is used to determine the early warning indicators. The initial warning stage, early warning indicator system, target business judgment stage, and accurate early warning stage of early indicators were described quantitatively to build a mathematical model.*

**Keywords:** pharmaceutical companies; patent infringement litigation; early warning indicators

## INTRODUCTION

With the accelerating process of economic globalization, Chinese pharmaceutical enterprises are facing more and more intellectual property disputes. In order to continue to maintain their own market dominance, original research enterprise use a variety of means to prevent or delay their opponents' similar drug to enter into market, such as filing a patent infringement lawsuit for generic drug companies. By establishing an effective platform of pharmaceutical patent infringement litigation early warning mechanism, we can prevent and respond to the growing number of intellectual property disputes and safeguard the economic security of Chinese pharmaceutical industry [1]. This can help pharmaceutical companies to effectively prevent patent litigation incentives. We plan to make a study about the possible incentives in patent infringement litigation and make a clear anticipation of legal actions through monitoring the context and trends in real time based on the establishment of early warning indicator system. According to Guo [2], patent infringement litigation incentives include the establishment of a pharmaceutical patent infringement litigation warning model, in order to reduce the patent infringement litigation warning costs and to improve the accuracy of the results of early warning. The early warning indicator system can be divided into three stages. The paper would make analysis of each of the three stages of the early warning indicator system on the above basis.

### 2. Initial warning stage of early warning indicators

This stage of early warning indicators is whether it is likely to face a patent infringement lawsuit. In the preliminary stages of early warning, the possibility of patent infringement litigation can be determined through the following warning indicators. If the possibility of occurrence of patent infringement litigation exceeds certain thresholds, it is believed that the possibility of experiencing a patent infringement lawsuit would enter into the judgment stage of the target company; otherwise, it is less likely to encounter a patent infringement lawsuit, thus terminating the early warning.

#### *2.1 Technology marketing stage of development indicators*

Technical fields stages of development indicators can reflect the intensity of market competition in the industry overall.

We use the second derivative of the industry production volume, the production rate of change, as the stage of

development indicators of the industry market. Assuming that industry production volume is *P*, then the industry market development milestone will satisfy:

$$a = \ddot{P}$$

where, a>0 indicates that production is growing, and a=0 shows a decline. When a<0, it indicates that the same yield as before for maintenance. In practical applications, we can select a smaller threshold *h* according to the characteristics of different industries. When $-h \le a \le h$, it is believed that the production is in the maintenance.

The judgment of the market development stage can be realized by analyzing the dynamic changes of the industry's main products: product curve is drawn based on the industry's major product changes in the statistical time as shown in Figure 1. If the curve gradually increases from zero and then increases progressively to a sudden burst, we can conclude that the indicator is growing in the strong momentum in the market development stage of the pharmaceutical industry which is in the emerging stage. If the curve goes from low to high, from high to balance, from balance to almost close to zero and continues for some time, we can conclude that the indicator of industry market development stage changes little and that the industry is in the growth stage or mature stage. If the curve is in the statistical time balance and declines from balance state, the development trend of the industry market stage is apparently decreasing. It is obvious that the industry is in the recession stage.

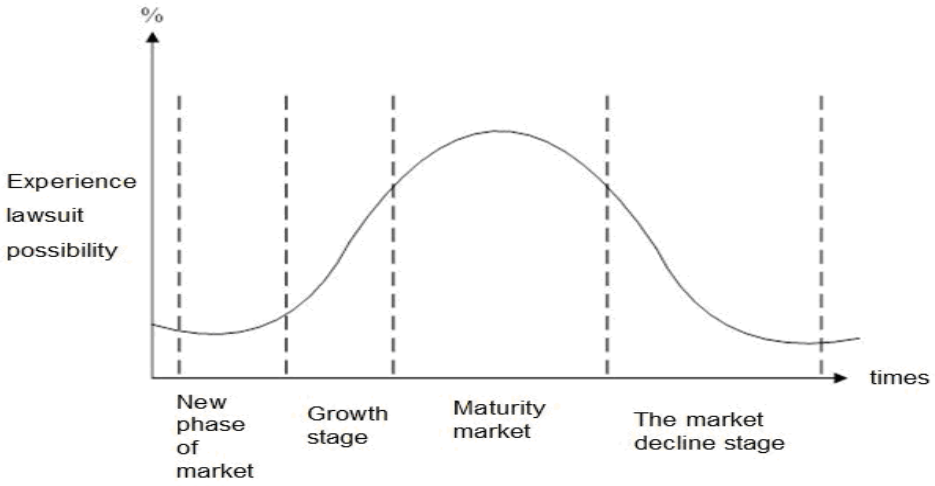


**Figure. 1 Industry development stage diagram**

*2.2 The number of patents granted in the field of medical technology*

The number of patents granted in the field of medical technology refers to the number of patents granted to the pharmaceutical industry in a particular time interval, and the index reflects the extent of the field of patent activity in the pharmaceutical industry overall. If a patent license exceeds to a certain extent, the industry belong to an active field and the pharmaceutical companies may encounter more patent barriers and technical barriers in the technology research and development, thus increasing the possibility of experiencing a patent infringement lawsuit.

*2.3 The field of medical technology patent growth rate indicators*

The growth rate of pharmaceutical industry patent is the percentage change of the number of patents increased over time, which can indicate whether the level of technological innovation is increasing. The change is used to calculate the speed of technological innovation at any time in an area of technology, industry or a country. This indicator can reflect on the overall rate of innovation of the pharmaceutical industry, in order to dynamically determine the infringement litigation risk the industry may face in the field. In addition, the indicators can be used for historical comparison to determine the trend of changes in this industry. If there is abnormal surging consistently for years, it shows that some company try to control patents in the field and are more likely to initiate patent infringement litigation [3].

Patent growth speed indicator is calculated as follows:

$$\varphi = \frac{T_k - T_{k-1}}{t}$$

where, $\varphi$ is the growth rate for patents, $T_k$ represents the amount of the patent period, $T_{k-1}$ represents the amount of patent authorization in the previous period, *t* is the time period. A is time period basis (for example 1 year), pre-patent license is the amount of patents granted in the selected time span from the starting point, the current

patents refer to patents granted in the end of the selected time span.

**3. The target company to determine the stage of early warning indicators**

This stage is the early warning indicators for enterprises that may file patent infringement lawsuits. At this stage, through identifying the patent monopoly companies in the field of medical technology, we can determine the likely initiated patent infringement litigation enterprise.

A patent monopoly companies in the surgery field can be determined by the "patent monopoly indicators". The patent monopoly indicator is a certain technology enterprise that has the largest amount of applications from the ratio of accounts for the total patent applications in the field. This indicator can reflect the degree of concentration of applications for patent in the field. In general, the greater the value of the patent monopoly indicators, the patentee has the higher the concentration of this technology. The company with high patent monopoly in the technology field has strong interests, and the motivation is strong to file a patent infringement lawsuit to safeguard their own interests. Therefore, we can analyze several companies through patent monopolies indicators to determine the potential company that might file patent infringement litigation to take into in the precise warning stage. For example, in 2010, the U.S. had 60588 patent applications, and Japanese patent applications reached 41917. As the second highest in the world of all countries, the EU-27 had 82,828 patent applications. In 2011, the top 10 pharmaceutical companies are Pfizer, Sanofi, Merck, Novartis, GlaxoSmithKline, Roche, AstraZeneca, Johnson & Johnson, Eli Lilly and Abbott, these companies' prescription drug sales have reached $ 346 billion, equivalent to 53% of the total income of the top 100 pharmaceutical companies. When carrying out the work of patent infringement litigation warning in China, you can target corporate positioning in these enterprises.

In the judgment stage of the target company, if there exists the possibility of the occurrence of patent infringement litigation, it would be transferred directly to the "alert stage", if not, the trade monopoly indicators and patent monopoly indicators to judge the industry key patent holders (which may be filed patent infringement lawsuits target company), and early warning enter go into the precise warning stage.

**4. Early warning indicators of accurate early warning stage**

At this stage, through the following warning indicators, it can be judged for the likelihood of a company to initiate patent infringement litigation.

*4.1 Company A's economic prospect indicator*

In order to suppress other competitors to achieve maximum profit, drug companies use various means to prevent or delay the opponent's similar drug to enter into the market, thus improving corporate economic prospect. One of the means is to provoke disputes and legal proceedings. To extend its own patent life and prevent or delay similar drug to enter the market, Pfizer and other companies tend to sue rivals for unfair competition. Patent disputes often require three years to settle. The report found that more than 60 percent of the defendant company will eventually win the case, which illustrates the plaintiff's purpose is to delay the time to market the generic drugs of the defendant company.

Company A growth rate g of the derivative for the economic prospect indicator *e*, to satisfy

$$e = \dot{g}$$

When e> 0, the annual growth rate of the target company is increasing, indicating that the enterprises operation is in good condition; when e <0, the annual growth rate is decreasing, indicating the poor condition of the business, thus generating a warning signal.

*4.2 The patent right protection of Company A in the country indicator*

Although the patent infringement litigation is a corporate behavior, the national patent protection on the one hand will affect patterns of behavior by litigation. On the other hand, the degree of consistent punishment of infringement will affect the expected results of patent infringement litigation. The degree of patent protection can be measured by the State Intellectual Property policy, the importance of intellectual property, drug supervision and management policies and regulatory dimensions of the national intellectual property system and trade policy measure. From the perspective of quantitative analysis, over a period of time, a national prosecution side to win a patent infringement litigation s and all patent infringement lawsuits *S* ratio can reflect the level of national patent protection to a certain extent, the index *p*

$$p = s/S$$

*4.3 A technical center of gravity indicators*

The percentage of patents requested of Company A in the field of medical technology to all patent applications in *C* is defined as technology center of gravity indicator *O*. It is for the judgment of Company A's focus.

$$O = c / C \times 100\%$$

*4.4 Company A's patent relative output indicators*

The proportion of patents granted to Company A in a technical field to all patents granted in the field is defined as a patent the relative number of indicators to assess the relative position of the company in the technology field.

$$R = b/T$$

where, *R* is the patent relative output indicators, *b* is Company A's patent applications in a technical field, *T* is the number of a technology patent applications.

*4.5 Patent impact indicators*

Patent impact indicators can be represented by the number of citation of a patent within a period of time relative to the whole number of the patent system that has been cited. The indicator reflects the level of activity of a patent in the relevant technical field, and the more it has been cited indicates that the patent is likely to contain important advantage of the technological development, and is good representatives of core technology in the related professional and technical areas, thus having a strong strategic value for enterprises. Such enterprises are often in a strong position in the industry.

*4.6 The technology patent life cycle indicators*

According to the dynamic changes of the patent applications, we can get a grasp of the life cycle in a technology field. The use of technology growth rate parameters can be clear and intuitive to reveal what stage of development a technology is in the life cycle [4].

$$g = b/\overline{b}_5$$

In the above equation *g* is the growth rate for technology, *b* is the number of patents for the year in a company, $\overline{b}_5$ is the cumulative number of patents in the retrospective five years. When *g* is increased in the calculation of the number of consecutive years, this indicates that the technology is in the nascent growth stage; if *g* has smaller fluctuations, it shows that the technology is in the mature stage; If *g* decreases, this indicates that the technology is at the stagnant stage. In the growth stage or mature stage of technology, the occurrence of patent infringement litigation is greatly possible. The reason of choosing five years as the patent cumulative number is that a technology industry development cycle is generally five years.

*4.7 Company B mainstream standard impact indicators*

Mainstream standard impact indicators reflect the ability of corporate control of mainstream standards. The smaller the value the company has, the greater the risk of patent infringement litigation of the company. As the standard-setting method which is usually adopted in the current international is patent pool, the number of patents of the influence of the mainstream standard is often determined by the number of patent which is absorbed by the standard patent pool.

$$M = P/P_a$$

where, *M* is the mainstream technology standards impact indicators, *P* is for the patent pool analysis to target the amount of the patent, $P_a$ is the average patent amount of the company patent pool.

*4.8 Company B's technology dependence indicator*

The indicators are for measuring the enterprise inventiveness. When an industry or enterprise has a strong technology-dependence in a technical field, this indicates that the independent development of new technical capabilities of the country's trade or business in this area is not strong, and the high value patent in the relevant technical field of a country's trade or business is not much. Thus, the enterprise is in the position of imitators and followers, and the technical competitiveness in the relevant field is weak. It is more likely to encounter competitors attempt to suppress. To the country's industry or enterprise in a technical field with the number of patents *L*, the countdown indicator for technology-dependent is l/L. The indicator is smaller when the number of patents owned by the indicators is more, and it shows that the technology-dependent of a technical field is low; the fewer the number of patents owned the company has a larger index, indicating technology-dependence in a technical field. When the number of patents in a technical field is zero, the index is infinite, indicating that a company in the field has no technical reserves.

*4.9 Company B's market share indicators*

This indicator reflects the share in a particular market for getting the percentage occupied by the products on the market. The larger this indicator is, the more prone a patent infringement lawsuit may be filed [5].

*4.10 Company B patent management maturity indicators*

This indicator can be measured by whether Company B has set a patent awareness, and whether it has implement a patent management strategies, and whether in the research and development, production and export was carried out before the patent information analysis was completed.

## CONCLUSION

In the initial stages of early warning, we can judge pharmaceutical market stage of development, the number of drug patents granted and the growth speed of patent granted through early warning indicators to judge the possibility of the occurrence of patent infringement litigation. Then by determining the existence of the patent monopoly in the field and other indicators, we can judge whether the enterprise may initiate patent infringement litigation. In the accurate early warning stage, we analyzed related indicators of enterprises which may initiate patent infringement litigation to determine the size of the possibility that the company may initiate suing and determine the potential patent litigation through the company's patent condition According to their own business determine the size of the enterprise may encounter the possibility of patent infringement litigation and related indicators of technology patents, thus completing the process of early warning of patent infringement litigation.

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