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Retrieving Patents: An Overview for Pharmaceutical Industry

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ABSTRACT

Patent system worldwide, as known today, is about two hundred years old and existed in some form at least about four hundred years ago in parts of Europe. However, over the last twenty years the volume of patents has grown phenomenally with interdisciplinary and complex subjects and the existence of internet makes most of the information available in some form or the other and has thus made the searchers' quest more difficult. Thus, patent search has attained much greater significance as it is always interlinked with commercial gains. India too has observed a quantum leap in patent applications in the last decade. Organisations are attaching greater importance to patent filing and thus for patent searching too. Patent search, as a profession has attained a significant position in the area of intellectual property .There has been several attempts to simplify and make the patent search more efficient and effective. The present paper provides an overview of the same.

Keywords: Patents searching, patent information system, online access, growth of patents in india, World Intellectual Property Organisation

1. INTRODUCTION

Patent systems were established by industrialised countries during the Industrial Revolution of the 18th and 19th centuries to provide incentive for the development of technology and also provide information to later inventors about the advances made by earlier innovators. The earliest patenting system was established in Italy in the 15th century followed by Great Britain in 1623[1].

Patent right enforcements were limited to control of the manufacture, use, and sale of the invention claimed in the patent. A patentee had the right to practice the claimed invention only if it did not require him to use inventions claimed in patents owned by others. The patentee has the right to license, reassign or sell the rights conferred by the patent and to sue for infringement, unauthorised manufacture, use or sale of a product, a process, or an apparatus covered by the patent claims.Patent systems require that the innovator discloses his innovation to obtain intellectual property rights. A patent right is for a limited period. In India, it is generally for 20 years from the date of filing. In the present international scenario, post the establishment of World Intellectual Property Organisation (WIPO), the grant of patent has been delinked from the life of patent. This was necessary as different countries take varying number of years for grant and thus resulting in substantially different patent life in different parts of the world for the same invention. Post the protection period, the patent is said to expire and the process and the end product can be freely used by anyone. In essence, it is a contract between the government and the inventor, wherein the inventor gets exclusivity for 20 years in lieu of full disclosure of the invention. Also, a patentee has the right to decide who may or may not use the invention for commercial purpose during the period for which the patent is protected.

2. INTERNATIONAL PATENT TREATISE TOWARDS HARMONISATION

Patent rights and collections of patent literature and documenting these rights have long existed in industrialised countries. Internationalisation of commerce in the late 19th century necessitated the filing of patent application in each of the country where the innovator wished to exclude others from practicing the invention,

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providing motivation for the formation of a treaty, to establish standardised treatment for patent applications.

2.1 Paris Convention

The earliest such treaty is the 'Paris Convention' first signed in 1883, that provides for acknowledgement of priority in the member states provided that the country of first application is also a member state, i.e., If a patentee files an application in one of the member countries, he could retain the same date of application and file in another member country, but within twelve months. India has been a member country of Paris Convention since December 1998.

2.2 World Intellectual Property Organisation

The WIPO is an intergovernmental organisation and is one of the 16 specialised agencies of the United Nations. The role of WIPO is to promote protection through co-operation among nations. The WIPO was established by the WIPO Convention in 1967 with a mandate from its member states to promote the protection of Intellectual Property throughout the world through cooperation among states and in collaboration with other international organisations. Its headquarter is in Geneva, Switzerland. The World Intellectual Property Organisation (WIPO) is a specialised agency dedicated to developing a balanced and accessible international intellectual property system, which rewards creativity, stimulates innovation and contributes to economic development while safeguarding the public interest.

The WIPO publishes and allows free access to all patent cooperation treaty (PCT) applications and the corresponding documents. Recently, it has added certain National applications and thus widened the scope of patent data available. The PCT is an international patent law treaty, signed by all WIPO members first agreed upon in 1970.

India signed the PCT agreement in December 1998. It provides a unified procedure for filing (http://en.wikipedia.org/wiki/Patent_applicationpatent) applications to protect (http://en.wikipedia.org/wiki/Invention) inventions in each of its Contracting States. A patent application filed under the PCT is called an international application or PCT application. As of June 2011, there are 144 Contracting States to the PCT[2].

2.3 World Trade Organisation & Trade Related Aspects of Intellectual Property Rights

The agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), an international agreement administered by the WTO (http://en.wikipedia.org/wiki/World_Trade_Organisation) that sets down minimum standards for intellectual property regulation came into force on 1st January 1995. In 2001, a meeting held in Doha issued a statement known as 'Doha Declaration' that addressed the concerns of developing countries including compulsory licensing. The member countries were provided adequate time to amend their local laws with the least developed nations being provided a period of 10 years until 2015 for implementation.

3. SELECT PRIMARY RESOURCES

3.1 Science Direct

The Science Direct[3] provides access to full-text contents of about 11,000 books and over 2500 journal published by Elsevier Science. The databases for books and journals are distinct from each other and are to be subscribed separately. It is one of the largest databases for primary information on chemistry and applied chemistry including pharmaceutical chemistry worldwide.

3.2 Wiley Online Library

Wiley Online Library[4] is one of the world's broadest and in-depth multidisciplinary collections of online resources covering life science, health science and physical sciences, social science, and the humanities. It provides access to over 4 million articles from 1500 journals, almost 10,000 online books, and hundreds of reference works, laboratory protocols and databases. It is of immense value to a patent searcher as it provides valuable primary information in the field of pharmaceutical chemistry. The database has a simple interface and delivers intuitive navigation, enhanced discoverability, expanded functionalities and a range of personalisation and alerting options.

3.3 United States Patent & Trademark Office

The United States Patent & Trademark Office (USPTO) is the Federal agency for granting United States patents and registering trademarks[5]. The USPTO fulfils the mandate of Article I, Section 8, Clause 8, of the Constitution[6] that the Executive branch 'promote the progress of science and the useful arts by securing for limited times to inventors the exclusive right to their respective discoveries'. The USPTO website provides free electronic copies of issued patents and patent applications as multiple-page TIFF (graphic) documents. The site also provides Boolean search option and analysis tools.

3.4 Espacenet (often written as *esp@cenet)*

A free online service for searching patents and patent applications, Espacenet[7] was developed by the European Patent Office (EPO) together with the member states of the European Patent Organisation in 1996. There are presently 38 member states. Every member state has an Espacenet service in its national language, and access to the EPO's worldwide database, most of which is in

English. Espacenet provides free access to more than 70 million patent documents worldwide containing information about inventions and technical developments from 1836 till date. Besides European patents, it also provides access to patents from most countries in the world including US, Canada, Japan, Korea, China and India.

4. SELECT SECONDARY SOURCES

4.1 *Index Medicus*

Index Medicus is a comprehensive index of medical scientific journal articles published since 1879[8]. It was initiated by J.S. Billings, head of the Library of the Surgeon General's Office, United States Army. This library later evolved into the United States National Library of Medicine (NLM), which continued publication of the Index. However, *Index Medicus* in the printed format ceased publication due to dwindling customer base and the online PubMed becoming more popular. PubMed is a free database accessing the MEDLINE database of citations, abstracts and some full-text articles on life sciences and biomedical topics. The United States NLM at the National Institutes of Health (NIH) maintains PubMed as part of the Entrez information retrieval system. It provides technical information which is crucial for any patent prior art search in the field of pharmaceutical sciences.

4.2 Beilstein

The Beilstein database[9] covers the subject of organic chemistry from 1771 to date. It contains over 9.8 million compounds, 10 million reactions (making it the world's largest reaction database) and 320 million experimental data on chemical properties. It also contains over 900,000 original author abstracts from 1980-present, as well as pharmacological and ecotoxicological data describing the bioactivity of organic chemicals. Since 2007, it is being published by Elsevier.

4.3 Ullmann's Encyclopedia of Industrial Chemistry

Ullmann's Encyclopedia of Industrial Chemistry from Wiley-VCH is the world's largest reference book in the areas of applied chemistry, industrial chemistry, and chemical engineering[10,11]. It was first published in 1914 in German and subsequent editions were also published in German. The 5th edition published in1985-1996 was the first edition in English. The subjects covered include agrochemicals, biochemistry & biotechnology, energy, cosmetics, fats and oils, polymers, plastics, metals and alloys and many more. It includes over 1000 articles written by more than 3000 experts and is considered to be the first-stop source for any query or question concerning chemicals, processes, physical and chemical data. It is available both in printed and online versions. It has about 50 articles devoted to pharmaceutical science besides several other articles on related subjects such as organic chemistry, polymers, biochemistry, etc.

4.4 Kirk-Othmer Encyclopedia of Chemical Technology

Kirk-Othmer also known as the 'most famous chemistry encyclopedia' and the single most valuable resource in a library's chemistry reference collection. It has proven to be a mainstay for chemists, biochemists, and engineers at academic, industrial, and government institutions since publication of the Ist edition in 1949. The 5th edition (2004-2007) includes necessary adjustments and modernisation of the content to reflect changes and developments in chemical technology. The scope includes over 1000 articles on chemical substances, properties, manufacturing, and uses. The topics relate to industrial processes, unit operations in chemical engineering; toxicology and health/safety aspects; economic data and uses[11]; handling, storage and regulatory information and fundamentals and related scientific subjects. It has nearly 100 articles devoted to pharmaceutical science.

5. PATENTING ACTIVITY IN INDIA

The rapid rise of India in the global economic landscape has dictated world's outlook towards India as a potential destination for research, development and innovation especially since it is known to be a low cost centre. A primary indicator of innovation is the number of patents filings. The number of patent applications filed at the Indian Patent Office has steadily increased over the years showing a steep increase since 2005. During 2009-10 over 34,000 patent applications were filed, while over 6,000 patents were granted. Of these granted patents, 530 were related to drugs and over 1800 were related to chemistry and biotechnology combined. Indian applications have risen steadily with about 2179 application in 2001-02 to about 7044 in 2009-2010[12].

The patent scenario in India as against some of the leading patent filing countries of the world is depicted in Table 1 below. The data is for the year 2008[13].

Table 1. Patent applications filed and Granted-India vs US, Japan. Korea, China, EPO

Country	No. of Patents	
	Applications filed	Granted
China	289,838	093,706
EPO	146,150	059,819
India	036,812	018,230
Japan	391,002	176,950
S Korea	170,632	083,523
USA	456,321	157,772

5.1 Patent Law

The earliest legislation in India relating to patents was the Act VI of 1856. The purpose of this legislation was to encourage inventions and induce inventors to disclose secret of their inventions. This act was subject to several amendments. The Patent & Designs Act of 1911 brought the administration of patents under the purview of Controller General of Patents, Designs & Trade Marks. This act was replaced much later by the Patent Act, 1970. A major change introduced in the act was absence of product patents with an aim to protect growth of indigenous industries and public interest. This act was in force for over 24 years and the changing economic scenario in the world warranted a change. A second amendment in 2003 introduced by way of Patent Rules, 2003.

The third amendment to the Patents Act 1970 was introduced through the Patents (Amendment) Ordinance, 2004. The Ordinance was later replaced by the Patents (Amendment) Act 2005 (on 4 April, 2005) which was brought into force with effect from 1 January 2005. The third amendment reintroduced product patents and was primarily aimed at fulfilling India's obligation under TRIPS.

Currently, patents in India are governed by the Patents Act, 1970 (No. 39 of 1970) as amended by the Patents (Amendment) Act, 2005 and the Patents Rules, 2003, as amended by the Patents (Amendment) Rules 2006 effective from 05 May 2006.

The pharmaceutical industry was at a great loss as they could not obtain monopoly over the products they developed[18]. This also ensured that there were few multinationals launching their products in India as they could not enforce their monopolistic rights over their product which had been developed by investing several millions of dollars. Thus, the reintroduction of product patents, in accordance with the TRIPS agreement, was of great significance to the pharmaceutical industry and is reflected in the number of patents filed.

5.2 Indian Patent Office

The Office of the Controller General of Patents, Designs & Trademarks (CGPDTM)[14] located at Mumbai is headed by Controller General of Patents, Designs, and Trade Marks. The Head Office of the Patent Office is at Kolkata and its Branch offices are located at Chennai, New Delhi and Mumbai where the Controller General is located. The Offices of The Patent Information System (PIS) and National Institute of Intellectual Property Management (NIIPM) are at Nagpur. The Controller General supervises the working of the Patents (Amendment) Act 2005, The Designs Act, 2000 and the Trade Marks Act, 1999 and also renders advice to the Government on matters relating to these subjects.

The Patent Office is currently in the process of making all its collection available online. A partial collection of published patent applications, granted patents and Controller General's decisions are available online and are searchable using multiple criteria such as inventor, application number, applicant, etc.The patent offices in India have regional jurisdiction. Companies/law firms registered in these regions have to file their patents in their respective regions only. Territorial jurisdiction of the appropriate office for the applicants is:

Office	Territorial jurisdiction
Patent Office, Kolkata	Head Patent Office. Covers all the regions in the country not covered by the other branch offices.
Patent Office Branch, Mumbai	Maharashtra, Gujarat, Madhya Pradesh, Goa and Chhattisgarh, Daman and Diu & Dadra and Nagar Haveli
Patent Office Branch, Chennai	Andhra Pradesh, Karnataka, Kerala, Tamil Nadu, Pondicherry and Lakshadweep
Patent Office Branch, Delhi	Haryana, Himachal Pradesh, Jammu and Kashmir, Punjab, Rajasthan, Uttar Pradesh, Uttaranchal, Delhi, Chandigarh.

5.2.1 Office of Patent Information System, Nagpur

The Government of India, Ministry of Commerce and Industry and Department of Industrial Policy and Promotion established Patent Information System (PIS), in 1980. PIS, Nagpur caters to user needs on the basis of patent documentation and computerised system for retrieval and dissemination of patent information. The objectives of PIS are:

- To obtain and maintain a comprehensive collection of patent specification and patent related literature on a worldwide basis to meet the needs for technological information, of various users in R&D establishments, Government Organisations, industries, business, inventors, and other users.
- To provide technological information contained in patents through, search services and patent copy supply service.

The PIS offers the following patent information services on payment of appropriate charges:

- State of Art Search
- Bibliographic Search
- English Equivalent Patent Search
- Equivalent Family Patent Search
- Assisted Search

The PIS also provides preliminary technical consultancy.

6. PATENTING PROCEDURE IN INDIA

An invention can be filed as a provisional patent application wherein a summary of the invention along with inventor and applicant details can be submitted at the Indian Patent Office. However, this has to be followed by filing of complete specification including examples/ experimental data and claims within 12 months. Alternately, a complete specification can be filed without filing a provisional specification. Once the application is filed, it is examined and then either granted or rejected.

The grant is published in the official gazette called the Patent Journal. There is a provision to challenge the patent after the grant, but within a period of 12 months. The patent application is also published with bibliographic details and abstract in the official gazette by the end of 18 months of filing. The application can then be challenged any time before grant under certain condition, by any party of interest. Once the grant has been intimated to the patentee, the patentee is expected to pay the required fees annually to keep the patent 'active' for its 20 year period. Any lapse on payment of requisite fee by the patentee, implies that the patent has lapsed and hence non-enforceable. A sharp increase has been observed in national phase applications through the PCT route-from 4164 in 2000-01 to 23431 applications in 2009-2010 and the rise is quite steep post 2005[15].The Indian Patent Office granted a record 98,881 patents during the period 2006-2009. A record 103,035 patent application were filed over the same period[16]. The number of granted patents and applications has reduced marginally in 2009-10 (Table 2).

Apart from manufacturing drugs, the product patent regime is likely to assist the pharmaceutical industry to tap outsourcing of clinical research. By participating in the international system of IPR protection, India, with its vast pool of scientific and technical personnel, and well-established expertise in medical treatment and health care, has unlocked vast opportunities in both exports and outsourcing and has the potential to become a global hub in the area of R&D-based clinical research. The Patent Ordinance also provides adequate safeguards to protect the interest of the domestic industry, and the citizen from any increase in prices of drugs.

Table 2. Patent applications filed vs granted

Year	No. of patents	
	Applications filed	Granted
1999-00	04824	01881
2000-01	08503	01318
2001-02	10592	01591
2002-03	11466	01379
2003-04	12613	02469
2004-05	17466	01911
2005-06	24505	04320
2006-07	28950	07539
2007-08	35218	15261
2008-09	36812	16061
2009-10	34287	06168

7. PRIOR ART SEARCHING

An integral aspect of patents is the prior art search. It is the search that determines whether a research project undertaken in an R&D or a new product developed is novel and inventive and hence eligible for a patent.

7.1 Pharmaceutical Industry and Information Retrieval

Pharmaceutical industry worldwide, as known today, was founded in the late 19th and early 20th centuries. Insulin and penicillin, some of the known discoveries of the 1920s and 1930s, came to be mass produced and distributed followed by several other drugs[17]. Following widespread sale and distribution, several countries formulated and enacted legislations to test and approve drugs. Drug companies differ from many other companies in the fact that the input costs are very high. For instance, only one out of every ten thousand discovered compounds actually becomes an approved drug for sale.

Companies spend millions of dollars in the early phases of development of compounds that will not become approved drugs. Hence, the drug industry adopts the strategy to protect its products and processes by means of patents to exercise monopoly and also recover the costs incurred.

The 20 billion USD Indian pharmaceutical industry has been growing at about 10 per cent rise in the last few years, especially since 2005, when India amended its Patent Act to grant product patents. Both multinational and Indian companies are progressively investing in research and filing patents on the new products and processes developed. Although the R&D expenditure of Indian companies averages at about less than 2 per cent there is an increasing interest in research and protecting its inventions[19,20].

It is difficult to determine the quantum of pharmaceutical patents as against the volume patents worldwide. Although total number of worldwide patents is easily obtained, no database or any literature was forthcoming regarding the number of pharmaceutical patents worldwide due to its overlap with other subjects such medical science, chemical sciences, and biotechnology. After several searches and communication with several database vendors, the relevant data could be obtained from Derwent World Patent Index through Thomson Reuters. It was found that of the current 78.8 million patents (2010) worldwide about 4 million relate to pharmaceutical chemistry. Thus about 5 per cent of worldwide patents are in the field of pharmaceutical

chemistry.Although there have been several studies done on prior art search and problems associated with searching, analysing and interpreting the search results, it is difficult to retrieve studies specifically on pharmaceutical industry and patents.

7.1.1 Methods for Searching and Analysing Pharmaceutical Patent Information

Calcagno[21] attempted to analyse pharmaceutical patents utilising the chemical structure information provided in Thomson's Derwent World Patent Index (DWPI). The article is an attempt to cluster chemical inventions using fragment descriptions provided by the Derwent chemical coding. Chemical structures in patents are, often a combination of many structures, some real, some prophetic, as represented by an entity called Markush structure. This entity is akin to a chemical compound library, and, indeed, usually incorporates both a 'scaffold' and substituent parts. Thus, the objective of analysing a set of patents can be more accurately described as that of analysing a set of Markush structures.

In addition, since a Markush structure is usually associated with a family of patents, the objective was more precisely defined as that of organising a set of inventions (patent families) according to their Markush structures. Further it also explores other directions in which this concept can be advanced. One could explore the plethora of clustering algorithms available including other hierarchical methods (e.g., ward, group average, bisecting Kmeans), non-hierarchical methods (e.g., Jarvis-Patrick, Kmeans), even fuzzy clustering (e.g., PC analysis and fuzzy kmeans), which allow multiple cluster membership.

According to a survey by Doganavsargil[22], one of the main reasons that discourages both current and potential users of patent information in reading the current awareness bulletins is that the search profiles do not focus well on their changing information needs. The users clearly expressed the need for new search profiles, as well as the need of being provided with patent information at different levels of detail. To appropriately suit the users' needs, a few profiles received more than just one level of detail. Dirnberger[23] compared different search strategies for establishing a focused patent landscape for the biotech drug human recombinant insulin in terms of the key indicators of patent search, quality, recall, and precision. The search strategies included pros and cons of 'crude and quick' vs. 'sophisticated' keyword search strategies. It has been observed that keyword in combination with sequence search strategies retrieve a highly precise set of documents.

Yang, *et al*[24] illustrate the use of a text mining tool to enhance patent analysis workflow to yield critical views of the data and actionable business intelligence. The two case studies relate to a subject area (Hepatitis C virus) and assessment of a company.

Although several studies have been conducted it was extremely difficult to obtain any specific study on pharmaceutical industry searching methodologies and issues. In India, pharmaceutical industry as one of the largest filer of patents also has a large number of litigations. In this context patent searching is of paramount importance. Companies such as Dr Reddy's and Ranbaxy are among the top patent filers in India and have dedicated teams for patent searching and filing and litigations. They are one of the largest and influential users of commercial databases for both chemistry and patents.

7.1.2 Issues in Prior Art Searching

There is a huge demand for patents in Indian pharma industry. However, on searching it was found that it was difficult to retrieve the number classified under pharmaceutical sciences from any of the commercial databases leave alone the free databases, and other primary resources. It was also observed that there is no parity in the classification codes used across the various databases. Although there are several commercial and free databases and patent offices providing information on patents and non-patent literature, the search is very complex[25].

As the subject matter of a patent is generally multidisciplinary and very specific nature, even classification search does not help at times. Also the fact that patents are filed in different languages[26,27] in different countries makes the search tedious and error prone. There are several new databases and resources made available in the recent past, which are trying to provide a solution. However, even today a patent searcher is never sure whether he has retrieved all patents in the subject of interest. Often the searcher goes by his experience rather than retrieved information. Hence, there is always an element of uncertainty.A sample comparison on number of hits retrieved while using classification tools was done:.The cassification codes were used for search as this method is known to be one of least error prone search method. Keywords and assignee/applicants etc can be different in different databases while the classification codes are standardised codes issued by designated authorities. To have a comprehensive and comparable result European Patent Classification (EPC) and International Patent Classification (IPC) were used. A combination of two Classification codes was used to reduce the number of retrieved results and obtain a set of focused documents. Classification codes used:

IPC (WIPO): A61K38/00 (Medicinal preparations containing peptide) & A61P3/10 (Special therapeutic

activity of chemical compounds-for hyperglycaemia, e.g: antidiabetic)

EPC (EPO): A61K38/00 (Medicinal preparations containing peptides) and A61K31 (Medicinal preparations containing organic active ingredient)

Classification Scheme	International Patent Classification	European Patent Classification
Class Number	A61K38/00 & A61P 3/10	A61K38/00 & A61K31
Total Patent	23297	795
Espacenet	16491	514
Thomson Innovation	21293	484
Patbase	03544	100

Accessed on 24 March 2011.

8. RESULTS

Apart from manufacturing drugs, the product patent regime is expected to aid the pharmaceutical industry to tap outsourcing of clinical research. By participating in the IPC and EPC were used as both the classification schemes were searchable across multiple databases and hence the differences in the results retrieved could be studied. However, the databases were selected such that they were as comprehensive as possible in terms of number of years and countries retrieved. Differences were observed between the free database (Espacenet) and the three commercial databases used, viz., Total Patent, Thomson Innovation and Patbase. There was a distinct difference in the number of patents retrieved, even between Espacenet and Thomson Innovation which are comparable in terms countries and years of coverage. The difference between these could be attributed to the indexing system used by Derwent Patent Index used by Thomson. Patbase retrieves only one entry per family and hence the number is lower.

Nijhof[28] proposed to define effective and efficient searching: i.e., find relevant documents fast. In general, the searcher should start as precisely as possible. Search the unusual terms. Search by AND-ing precise words (or phrases) and/or classes. Then expand carefully: start searching abstracts or claims before turning to full-text searching. Further work down from the high precision words and classes to the lower precision words and classes. Also citation and company or inventor name searches may be of help to carefully expand the collection of publications for review. Although these recommended procedures and theories may seem to be simple reading material, they require training and management to be able to properly use these in practice.

9. CONCLUSIONS

System of IPR protection, India, with its vast pool of scientific and technical personnel, and well-established expertise in medical treatment and healthcare, has unlocked vast opportunities in both exports and outsourcing and has the potential to become a global hub in the area of R&D-based clinical research. The Patent Ordinance also provides adequate safeguards to protect the interest of domestic industry, and the general public from any hike in drug prices. Multinational companies in pharmaceutical industry had maintained a low-key presence in the Indian market due to rigid price control and absence of product patents. However, the change is evident in the substantial increase in number of patents filed and granted at the Indian Patent Office in the last few years. The online patent database from the Indian Patent Office is still being developed and proves to be a hurdle for prior art searching and India has still a long way to achieve an effective system for prior art search both for patent and non-patent literature. Thus, there is a need to study the tools available for patent searching and an efficient search methodology to retrieve an effective result.

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