

# Risk Assessment

## Using Patent Landscape Mapping to Identify Specialty Pharma Opportunities

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### Introduction

Patent Landscape Mapping (PLM) is a tool to analyze existing intellectual property (IP) to determine the risks and opportunities of participating in a given technology and/or product space. It describes the technologies and alternative solutions that have been applied to a particular product category. PLM identifies competitors based on their issued and filed IP, and outlines their strategies, strengths, and problem-solving approaches. PLM enables a company's scientific and commercial management teams to identify the best opportunities for investment in a selected product area, to create a strategy to protect their IP, and to establish differentiation with respect to their competitors. PLM uses sophisticated patent-searching techniques to explore multiple technologies that are available to solve a problem, such as the treatment of a particular disease state. It provides a

summary of the different approaches that have been applied and outlines strategic trends, including the innovation pace of the technological field, the geographic distribution of the current patent holders, and the leading IP in the field based on the rate of reference by later inventors. PLM characterizes competitors' positioning in the field and their level of threat to others based on a number of comparative measurements. PLM provides recommendations for entry strategy and licensing/acquisition targets. The results of the PLM analysis are presented in a user-friendly graphical format that includes a patent landscape contour map along with a written explanation. The contour map is especially valuable in that it provides a summary of complex technical information in an at-a-glance view of the entire IP landscape. Patent Landscape Mapping differs from traditional technology assessments that are focused on a single patent or several closely related patents.

The technology assessment provides an analysis of the claims of a given patent or patents and determines if these claims are sufficient to protect a given product or product concept. PLM should also not be viewed as a substitute for other IP investigations, such as freedom-to-operate, patentability, validity, or infringement analyses, but is in fact complementary to them. The primary focus of these other IP investigations is to analyze the claims of several patents to determine if and how much they overlap with each other. PLM, on the other hand, analyzes numerous patents representing similar and alternative approaches associated with a technological field and extracts strategic, competitive, and technical trends from the patents. Different patent search strategies, examination efforts, and depths of detail gathering are applied according to the particular purpose of one of these investigations.

Before exploring PLM's application to Specialty Pharma, let's look at the evolution of Specialty Pharma and the various types of companies within the sector. Throughout the past 10 to 15 years, Specialty Pharma has earned recognition as a distinct segment of the pharmaceutical industry. Specialty Pharmaceutical products have always existed, as have small to mid-size pharmaceutical companies. Nevertheless, the evolution of Specialty Pharmaceuticals into a segment of its own was driven by the void that developed after Big Pharma's business model began to focus on hiring mega-sized sales forces to promote

## Matrix of Companies by Technology (Example)

Category	Technology	No. of Items	Company						All Other
			A	B	C	D	E	F	
Chemical Formulation	Imidazole	20	6		7	6	1		0
	Peroxide	11		2					9
	pH Control	7			3			1	3
Biological Formulation	Bacterial	28	1			1	6		20
	Botanic Extract	11							11
Hormonal Formulation		7		2					5
Drug Delivery	Insert	9	4						5
	Ointment or Suppository	4						1	3
	Douche	8							8
	Polymeric Release	22	1	7				2	12

Table 1.

blockbuster products to primary care physicians. In order to sustain their accelerating growth rates in the face of patent expirations and pipelines that could not constantly churn out billion-dollar products, Big Pharma companies began to merge in order to effectively share pipelines and in theory, to generate greater numbers of blockbuster products at a reduced cost. This resulted in the creation of an opportunity space for companies specializing in smaller products having narrower target markets. Traditionally, Specialty Pharma companies have been defined as those that benefit strategically by using a relatively small, focused sales force to call on the practitioners of a specific medical specialty. In practice, Specialty Pharmaceutical companies have adopted various business models, and in many cases, being a Specialty Pharmaceutical company is merely a function of size or a growth stage in a company's own life cycle. For example, a drug delivery company may aspire to become more fully integrated by developing its own products to compete in a specialty area. A more or less fully integrated Specialty Pharmaceutical

company may aspire to evolve into the Big Pharma arena as one or more of its products attain franchise status. Well-known examples of the former and latter are Alza (prior to its acquisition by Johnson and Johnson) and Forest Laboratories, respectively. For purposes relating to PLM, we define the types of Specialty Pharmaceutical companies as:

- Drug Delivery Oriented
- Product Development Oriented
- Marketing & Sales Oriented
- Fully Integrated

## Patent Landscape Mapping Searching Methods

As an example, consider that a Specialty Pharmaceutical company with a focus on women's health care wants to participate in the market for the treatment of the vaginal Candida (yeast) infection that is extremely common in women. Using PLM, the company can identify the pertinent intellectual property associated with key product parameters. In this example, a total of 9 distinct search queries were conducted including keyword, semantic, and

International Patent Classification (IPC) searches. The United States, European, and World Intellectual Property Organization patent databases covering a relevant timeframe were examined. Approximately 1,700 patents and published applications were found and subjected to patent screening based on their relevancy to Candida infection treatment technologies. The screening methods that sort similar patents into groups and examine patent content on an individual basis identified more than 200 highly relevant patents and published applications that were the basis for determining the key product parameters. The employment of different search methods and multiple search queries are essential to obtain a comprehensive and objective view of the patent landscape.

## Key Product Parameters

One of the key parameters that was identified through the examination of the relevant granted patents and published applications is the type of agent used to treat Candida infection. The following three types — chemical, biological, and hormonal — were identified:

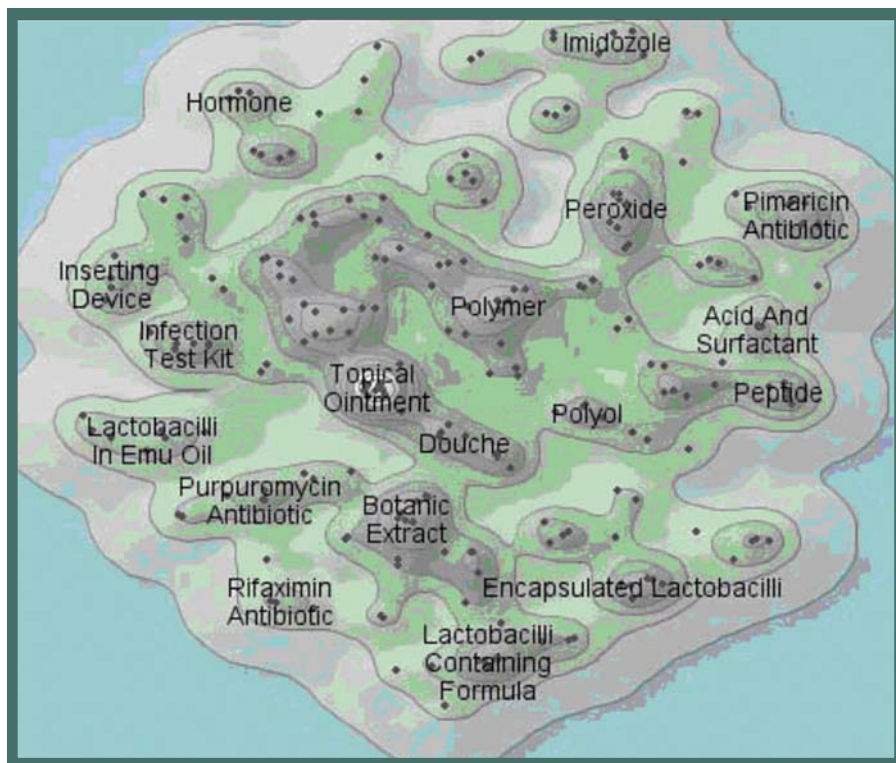


Figure 1.

**1. Chemical** – Included are imidazole agents, such as miconazole used in Monistat®, as well as peroxide and pH-controlling agents;

**2. Biological** – Includes naturally occurring bacteria, botanical extracts, and other biological molecules for inhibiting fungal growth; and

**3. Hormonal** – Estrogen, estrogen agonist/antagonists, and prostaglandins that are often used to treat conditions, such as sexual dysfunction or hormone imbalance may also provide vaginal Candida infection treatment.

Another key parameter identified was the choice of a delivery system used to administer the selected agent. Examples include the following:

1. Removable insert, such as a tampon, sponge, or a special syringe;
2. Douche;
3. Ointment or cream;
4. Suppository;
5. Polymeric film delivery system; and

6. Polymeric controlled-release matrix of another type.

## Mapping of Key Product Parameters

The key product parameters identified by the search process can then be represented by a terrain-like map that not only identifies the subjects of various patents and patent applications, but also displays the relative patent densities (Figure 1). Each dot in the map represents a granted patent or patent application. Items having similar contents form a contour circle representing a specific topic. The relative closeness of the dots and circles to one another indicates the similarity of the patent content. The color of the contour corresponds to a relative patent density, ie, blue or light green representing open space; dark green, moderately populated; and white, highly populated. The key product parameters can then be organized into technology

categories corresponding to: 1) chemical formulation; 2) biological formulation; 3) hormonal formulation; and 4) drug delivery system.

Also of importance are patent activity trends. Figure 2 illustrates the active patent areas between 1977 and 2005. Newer evolving technology can be differentiated from older approaches. Based on the observed patents, treatment technology evolved from the antibiotic-based agents (teal dots) during the 1970s to early 1990s, to the naturally occurring bacterial agents (yellow dots) during the mid- to late-1990s, and then was concentrated in the imidazole class of agents (green dots) during 2000 to 2002. Drug delivery systems, defined by the contour line near the center of the map, have attracted consistent interest throughout. Additional outputs useful for market analysis and for determining licensing targets include a list of the top companies by patent portfolio size (Figure 3) and a matrix of companies by technology (Table 1). These data will help a Specialty Pharmaceutical company identify the specific technology(s) that its competitors or potential competitors are pursuing and will help clarify the opportunity space and evaluate the risks for its own intended product.

## Using PLM

Let us now consider how the various types of Specialty Pharmaceutical companies would use the information generated using PLM analysis.

### Drug Delivery

Drug delivery companies provide the pharmaceutical formulation development of a product, whether it is a traditional dosage or a unique delivery system offering specific targeting and/or release properties. These companies are extremely conscious of their own and competing IP, as this protects the commercial viability of their

technology and is the basis for the revenue generated by their licensing programs. Specific uses leading to an analysis of the opportunity space are as follows:

1. A drug delivery company can survey and examine the technologies of competing companies, ie, a company having a film technology can determine how its IP/technology differs from another film development company. This can apply to composition, properties, manufacturing processes, and other unique claims, and can assist in ensuring non-infringement.
2. Continuing with the Candida example, a company seeking to develop a vaginal film delivery system can determine if other companies have done the same. Is there an opportunity for a particular use patent that could protect the product area?
3. In conjunction with a specific technical assessment, a drug delivery company can determine how to

engineer its way around existing patents when engaging in its own formulation/system development. These types of patents often constitute the essential barriers to the development of alternative or generic products because the new chemical entity patents have either expired or will expire soon.

### Product Development Oriented (PDO)

For the purpose of this article, a PDO company is involved with the clinical development of a product. These may be early-stage companies that are postponing the formation of marketing and sales functions until FDA approval of one of their products is foreseeable. The company will be interested in PLM analysis from the standpoint of project/product selection and clinical alternatives. Specific uses are:

1. The at-a-glance view afforded by PLM is very useful in determining the IP covering various treatments for a given disease state. The most prevalent areas

and trends are identified. The opportunity space for developing products with significant IP protection can be identified.

2. IP gaps can be spotted and opportunities for in-licensing and out-licensing can be identified. The deployment of a combined IP building and licensing strategy permits significant savings in R&D while the ultimate objective of developing a viable commercial product is secured. This enables a PDO company to maximize the value of its IP portfolio while at the same time creating new product development candidates.
3. The IP that a PDO company comes to possess is subsequently of enormous value in generating revenue by licensing its fully developed product for marketing and is a significant basis for the assets of the firm.

### Marketing and Sales Oriented (MSO)

In this analysis, the MSO company does not develop products. Its business model is to license and/or acquire products. These products constitute the pipeline for its highly effective marketing and sales infrastructure. Thus, the IP covering a given product or product area must be secure in order for an MSO company to justify the investment of its commercial resources. Specific uses are as follows:

1. A primary value of PLM to the MSO company is to screen acquisition and license targets. The IP of potential licensors and acquisition targets can be compared at-a-glance to that of competitors and potential competitors. For example, an MSO firm interested in marketing a biological formulation for treating Candida can determine which potential licensors have IP that is not utilized in a commercially optimal manner. They can then be approached by the MSO company.

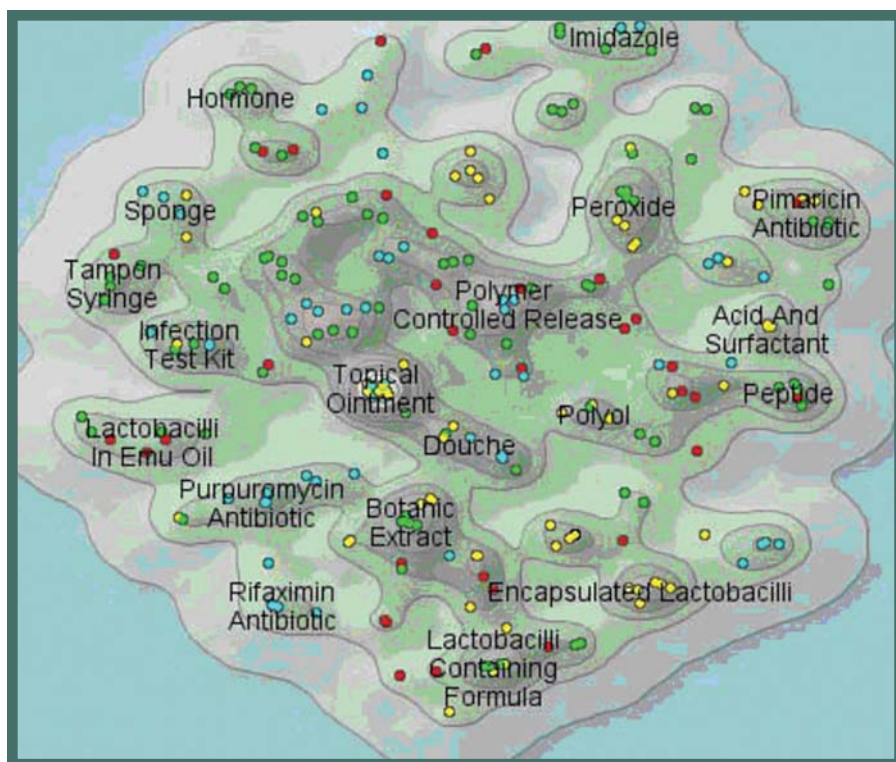


Figure 2.

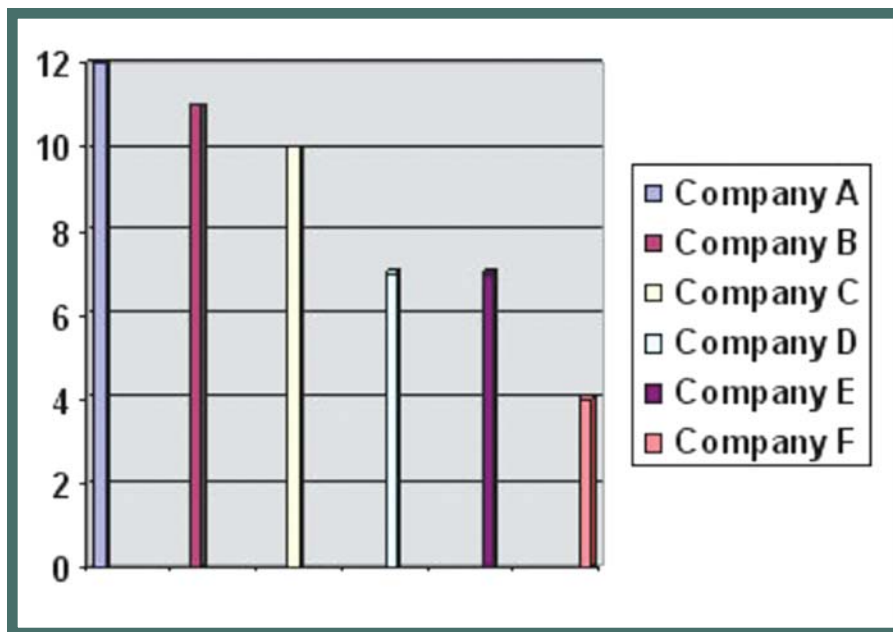


Figure 3.

2. In addition to the identification of product targets, PLM analysis is extremely useful in the due diligence phase of a transaction and as an effective tool in the IP valuation process. The at-a-glance view and trend data offer strategic understanding of the targets' IP positioning in the field relative to other competitors, thus optimizing an MSO company's opportunity to invest in a winning product.

### Fully Integrated Specialty Pharmaceutical Companies

The activities of a fully integrated company will encompass many or all of the above functions plus manufacturing. Thus, a fully integrated company will clearly benefit from the applications of PLM previously described. By participating in the overall process of bringing a drug product to market, a fully integrated company has even greater opportunity to use PLM as a tool to manage its IP portfolio and identify product opportunities.

### Summary

A company can use Patent Landscape Mapping to help ensure the economic value of its IP and the IP it may license. It can detect threats to its products and markets and learn how to circumvent them. PLM enables a company to profit from intellectual property value through defensive and/or offensive approaches. When planning to invest millions of dollars and years of effort in a new product development, licensing or acquisition opportunity, Patent Landscape Mapping is an enormously valuable tool to identify the strategic, technical, and competitive implications of the intellectual property landscape so that a product can be fully protected and positioned properly in the market. ■



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