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Recent Trends in Specialty Pharma Business Model

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Abstract: *The recent rise of specialty pharma is attributed to its flexible, versatile, and open business model while the traditional big pharma is facing a challenging time with patent cliff, generic threat, and low research and development (R&D) productivity. These multinational pharmaceutical companies, facing a difficult time, have been systematically externalizing R&D and some even establish their own corporate venture capital so as to diversify with more shots on goal, with the hope of achieving a higher success rate in their compound pipeline. Biologics and clinical Phase II proof-of-concept (POC) compounds are the preferred licensing and collaboration targets. Biologics enjoys a high success rate with a low generic biosimilar threat, while the need is high for clinical Phase II POC compounds, due to its high attrition/low success rate. Repurposing of big pharma leftover compounds is a popular strategy but with limitations. Most old compounds come with baggage either in lackluster clinical performance or short in patent life. Orphan drugs is another area which has gained popularity in recent years. The shorter and less costly regulatory pathway provides incentives, especially for smaller specialty pharma. However, clinical studies on orphan drugs require a large network of clinical operations in many countries in order to recruit enough patients. Big pharma is also working on orphan drugs starting with a small indication, with the hope of expanding the indication into a blockbuster status. Specialty medicine, including orphan drugs, has become the growth engine in the pharmaceutical industry worldwide. Big pharma is also keen on in-licensing technology or projects from specialty pharma to extend product life cycles, in order to protect their blockbuster drug franchises. Ample opportunities exist for smaller players, even in the emerging countries, to collaborate with multinational pharmaceutical companies provided that the technology platforms or specialty medicinal products are what the big pharma wants. The understanding of intellectual properties and international drug regulations are the key for specialty pharma to have a workable strategy for product registration worldwide.*

Keywords: corporate venture, intellectual property, open innovation.

I. INTRODUCTION

"What is specialty pharma?" many people question me. Is it in-licensing specialists? Niche marketers? Drug delivery firms? Will generic drug manufacturers be included? How about biotech companies that move into drug development? Well, depending on whom you ask, they are all of the above. Wall Street's definition is a catch-all, and includes drug delivery, biotech, and generic firms. For instance, Morgan Stanley coverage of specialty pharma includes: generic companies like Teva, Mylan, and Actavis; over the counter companies like Perrigo and Warner Chilcott; development centric companies like Allergan, Forest, and Valeant (previously Bio vail); drug delivery companies like Alkermes; and animal healthcare company like Zoetis (formerly Pfizer animal healthcare division). As the popularity of the specialty pharma business model has expanded, so has its scope. Today, many use the term "specialty pharma" interchange ably with development-centric pharmaceutical or biopharmaceutical companies. Others apply it to companies developing generics, reformulating existing drugs, or targeting niche markets. Some others more often use the term to identify companies that are "not biotech not big pharma", where big pharma is defined as large-cap pharmaceutical companies. In other words, "specialty pharma" has become such a broad term that it covers just about everything except the big pharmaceutical companies and medical device and diagnostic makers.

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II. SPECIALTY PHARMA BUSINESS MODEL

After defining specialty pharma is inclusive of all healthcare related firms that are neither big pharma houses nor medical device and diagnostic makers, the next question is "What is specialty pharma's business model and why it gains so much popularity nowadays?" In order to answer these questions, it is necessary to compare and contrast big pharma with specialty pharma. Big pharma typically follows a vertically integrated business model. It means that big pharma carries out the work from the beginning to the end on a worldwide scale including discovery research, drug synthesis, preclinical research, clinical development, regulatory work, scale up and manufacturing, and worldwide distribution, sales, and marketing. Moreover, big pharma has more breadth by working in four to six therapeutic areas. These may include cardiovascular, antimetabolite (such as antidiabetics), central nervous system (CNS), oncology, and infectious diseases. Specialty pharma, by contrast, acquires drugs from academia, research institutions, or other companies, and seeks to commercialize them in new markets. It selects a core of activities while relying on a network of contract research organizations (CRO), contract manufacturing organizations (CMO), and other preferred pharma partners to accomplish its commercial goal. Specialty pharma focuses most of its efforts on one or two therapeutic areas with specified physician populations. These specialized nonprimary care physicians can be managed with a smaller sales force. Specialty pharma often has a small research and development (R&D) organization and contracts out animal and human tastings to CRO and its manufacturing to CMO. It is a business model that has been prevalent in the last years as venture investors seek to find a way around the long, expensive, and risky drug discovery process. The attributes of specialty pharma are "small", "niche", "agile", and "focused" that are popular with Wall Street.

III. FOUR CATEGORIES OF SPECIALTY PHARMA

The business model of specialty pharma can be divided into four categories. Some companies are experts in the search of compounds for in-licensing; some focus on marketing specialty medicines to a limited number of clients; some started as a generic company; and some with a specific delivery technology knowhow. The world largest generic company, Teva ("Nature" in Hebrew) is on the list of specialty pharma. In fact, the largest product of Teva is a specialty brand medicine, glatiramer (Copaxone), which constitutes nearly 50% of profit and 20% of revenue which is $20.3 billion in 2012. Glatiramer, the most popular multiple sclerosis drug, was originally discovered by three professors at the Weizmann Institute of Science in Israel. It is a random polymer (6.4 kD) composed of four amino acids (namely glutamic acid, lysine, alanine, and tyrosine) that are found in myelin basic protein [4]. Administration of glatiramer shifts the population of T cells from pro-inflammatory Th1 cells to regulatory Th2 cells that suppress the inflammatory response. Given its resemblance to myelin basic protein, glatiramer may have acted as a decoy, diverting the autoimmune responses against myelin. Glatiramer was approved in 1996 in the US and in 2000 in the EU. It is currently marketed in 49 countries.

Innovator's life cycle management opportunities

Life cycle management of on-patent pharmaceuticals has become increasingly important to big pharma since it is more and more difficult to replace off-patent drugs with new blockbusters, as they are challenged to meet revenue and profit growth expectations. Given this environment, companies have started and been successful not only internally, but also at in-licensing technology or projects from specialty pharma for the protection of the life cycles of their blockbuster drug franchises. The study of life cycle management consequently becomes the focus for a subset of specialty pharma specializing in drug delivery platforms and for another subset of specialty pharma concentrating on old drug, new use, especially if the old drug is a blockbuster from a large pharma. The innovator, relying on their own proprietary preclinical and clinical data in the original NDA, can supplement the original NDA and obtain a license for an improved version oftheir own drug [10]. Whereas for the specialty pharma working on an improved version of the other's drug, the regulatory filing route is NDA 505(b)(2) that requires patent certification of non-infringement to the innovator's patent, in order to rely on the safety and efficacy data filed in the original NDA for the approval of the improved version of the old drug [78]. In this process, inefficiency may kick, in since the specialty pharma is not privy to the innovator's database leading to possible erroneous assumptions and repetitive guesswork. Therefore, it is beneficial to approach the potential customers for one's technology and project ideas before investing significant money in the type of life cycle management projects. The other advantage for the specialty pharma to collaborate with the

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innovator is to capitalize on the innovator's infrastructure of marketing and sales. It is resource intensive if not impossible, to launch a product when the innovator holds fast to the target patient population. The key to secure the innovator's interest in one''s technology would be the demonstrable clinical advantages of the improved version over the old version.

Intellectual property strategies

In assessing different technology approaches to old drug, new use, companies need to consider several factors on a molecule-by-molecule basis. First and foremost, they will have to be confident that there is a potential for clinical improvement of the original molecule through reformulation and/or chemical modification. Companies must also consider their tolerance for risk and willingness to invest in either less proven technologies and/or radical modifications of the original molecule, as the old saying the idea of being able to achieve rewards without the risk is not sustainable. Finally, the distinctiveness of the technology, including the intellectual property situation, must be carefully assessed. The patents derived from product life cycle management are called ancillary patents, which are distinct from the basic compound patents. The ancillary patents range from polymorph, salt, formulation, prodrug, delivery device, new indication, alternative route of administration, to new method of use. In general, the ancillary patents, particularly if the new product patent expires later than the original patent, are weaker and attract more patent challenges from generic competitions.

IV. CONCLUSION

The global trends of open innovation, fast growing emerging markets, and patent cliff threat provides ample opportunity for smaller specialty pharma companies to gain the upper
hand provided that the technology platforms or specialty medicinal products is what the big pharma wants. The easy around the clock internet telecommunication also provides the specialty pharma in emerging countries with opportunities to merge or work with western big pharma on the wide spanning niche products and the opportunity to improve the use of old drugs. It takes one to evaluate one's own strength and weakness to strategically select partners with complimenting strengths, in order to maximize the probability of success. However, this vast opportunity is not endless. The rise of densely populated countries such as India and China is going to accelerate the competition in the pharmaceutical industry worldwide. Smaller players in smaller countries with no domestic demands will eventually lose out to the big players in big countries, except for the ones with the vision to collaborate with the stronger to make themselves strong.

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