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An exploratory analysis of patent fencing in pharmaceuticals: The case of PDE5 inhibitors

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ABSTRACT

Firms pursue a number of strategies to appropriate value, including patenting. In this paper I study patent fencing, a specific filing strategy to use multiple related patents to further enhance value appropriation. The paper addresses the pharmaceutical industry, which shows a high patenting propensity and strong lifecycle management activities leading to additional patent filings per drug. Building on an inductive case study, this paper explores the mechanisms behind patent fencing within a novel class of drugs. Patents with offensive blocking potential are primarily filed in the a later stage of the lifecycle and are tied to certain categories of patents with a low potential to substitute prior filings economically, while filing of patents with defensive blocking potential occurs more often in the early lifecycle stage. Finally, a model is developed on patent fencing in pharmaceuticals that builds on these patents' characteristics.

1. Introduction

Firms strive to better appropriate value through a range of activities, including legal measures such as trademarks, copyrights, and patents, and strategies building on secrecy, complexity, and lead time advantages (Arundel et al., 1995; Cohen et al., 2000; Levin et al., 1987). In this context, patents have received much attention (see, e.g., Ceccagnoli, 2009; Ernst, 2001; Markman et al., 2004), providing at least some imitation protection that yields short exclusivity periods on the market before competitors introduce their products, as well as creating higher imitation costs (Mansfield et al., 1981). Because even such short temporal advantages may be highly profitable in pharmaceuticals, where a few patents may protect products with billions of dollars in revenues, and patent protection is particularly effective, the patent propensity is relatively high here (Arundel and Kabla, 1998). In fact, without patent protection, many pharmaceutical innovations would not exist (Mansfield, 1986).

The literature on patenting strategies mentions approaches that use multiple patents to create fences, further enhancing value appropriation (Granstrand, 1999; Rahn, 1994; Rivette and Kline, 2000). To date, however, little is known about how such patent fences are erected and how they interfere with drug lifecycle management, which involves different categories of patents to further protect a drug, including processes, novel formulations, or indications (Bhat, 2005; Howard, 2007; Hutchins, 2003; Whitehead et al., 2008). Apart from these categories, filing strategies that might play a role when creating patent fences include timing of patent filings, exploiting the complementary or substitutive nature of patents (Cohen et al., 2000; Reitzig, 2004), and designing patents in such a way that they protect from imitation or block competitors (Blind et al., 2006). Although these factors have partially been described in isolation, it is still unclear how they may be used in combination to create patent fences. To date, the ways in which pharmaceutical companies orchestrate their patent filing strategies remain to be fully described.

To elicit which filing patterns are engaged by pharmaceutical firms, I chose an inductive case study method, investigating patenting activities of three firms that each introduced new products within a newly established class of drug. More specifically, I studied the field of PDE5 (phosphodiesterase type 5) inhibitors, with 2010 revenues of approximately US $5 billion; these products are among the most widely counterfeited in the world. The research setting allowed me to study the patenting activities of a market leader and two followers that introduced their products five years after the first firm introduced its drug, thereby gaining significant market share. The dataset involves longitudinal data that facilitate the understanding of potentially significant temporal patterns in the filing process, while also reflecting attempts to keep both original and generic drug makers at distance. It also allowed me to conduct content analysis of patent claims, eliciting the degree to which patent filings related to substances, processes, or novel

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indications; and, jointly with data from a chemical database, assessing the extent to which blocking of competitors took place.

My findings reveal that in the early stage of drug lifecycle management, patents with blocking potential were primarily defensive in nature, while later patents with blocking potential were more offensive, involving some particular patent categories. The results also show that many patents are formulated in a way that prevents imitation and blocks competitors at the same time, while some allow substituting prior patents from an economical perspective to a higher degree than others. Taken together, these findings enhance the prior literature on appropriation strategies. In addition, I develop a model showing how patent fencing took place, including filing motives, timing, categories of patents, and their potential to economically substitutive prior filings.

The next section of the paper explains the different facets of patent filings in detail, followed by a section on drug lifecycle management. Section 4 introduces the dataset, case setting, and methodology. The case analysis is presented in Section 5. The model derived from the case is presented in Section 6, followed by discussions.

2. Complementary, substitutability, imitation protection, and blocking

Prior work on patent management describes a range of patenting strategies aimed at further appropriating value by building clusters of patents (Granstrand, 1999; Rahn, 1994; Rivette and Kline, 2000). These include blanketing or flooding, where a certain technological space is covered by various patents in a rather unsystematic way; fencing—i.e., filing multiple patents that describe different technological solutions for similar functional outcomes (Granstrand, 1999); surrounding, in which a basic patent is surrounded by a competitor's picket fence, and patent networks, such as a certain setup of a portfolio to enhance its overall strength. Among them, patent fencing is a strategy that has also received the most attention in the scholarly literature (Reitzig, 2004; Ziedonis, 2004).

The Carnegie Mellon Survey (CMS) (Cohen et al., 2000) more precisely defines patent fencing as follows: "[. . .] fence building involves the patenting, though not licensing (nor necessarily even commercializing), of variants and other inventions that might substitute for the core innovation in order to preempt rivals from introducing competing innovations." (p. 25). This survey uncovered patent fencing tendencies across a range of industries. While the petroleum, steel, machinery, computer, and electronics industries hardly create any patent fences following this definition, the practice is widespread in the textile, paper, and chemical industries, with intermediate levels in the printing, drug, and medical industries. Filing different patents for a drug is widely perceived as fencing within the pharmaceutical industry (see e.g., European Generic Medicines Association). This may, in particular, involve filings shaped by lifecycle management activities.

The prior literature argues that patents employed for fencing are substitutive (Cohen et al., 2000; Granstrand, 1999; Reitzig, 2004). However, complementarity and substitutability are a matter of perspective: One example is patent A, which relates to substance X; patent B, which relates to a novel formulation 1 of a pill with substance X; and patent C, which protects an alternative formulation 2 of a pill with substance X. So, all patents overlap regarding substance X. From a legal perspective, patents B and C each cover one subdomain of patent A, and patents B and C technologically extend patent A, implying technological complementarity in the relationships A–B and A–C. In addition, the relationship B–C implies technological substitutability. However, one need only possess one of the patents A and B or A and C to block the marketing of the formulations 1 and 2, respectively, each incorporated into a pill with substance X. So, legally, the patents A and B as well as A and C are substitutes, while B and C are complements (as one needs to possess both to prevent marketing these novel formulations).

At least two important boundary conditions are associated with these perspectives. First, the legal breadth of the overlap between the patents determines the economic impact of legal complementarity or substitutability: let us assume that patent D is a substance patent, and patent E is a patent that claims a particular use of the same substance. Then, following the arguments above, these patents are substitutes from a legal perspective. They, however, might not be substitutes from an economic perspective. If the substance alone can address a market potential across multiple uses of, say, $100 million, the specific use mentioned in patent E may cover only a market of $20 million. So while technological complementarity and legal substitutability are given, no full economical substitutability can be achieved.

The second boundary condition is ownership of the property rights. When technological complementarity exists and the patents are usually distributed among different owners, then the situation is frequently described as a patent thicket, with mutual blocking potential of the parties (Christie and Dent, 2010; Clarkson and DeKorte, 2006; Cohen et al., 2000; Reitzig, 2004).[1]

Imitation protection is the most important motive for filing patents in the pharmaceutical industry, followed by blocking competitors (Blind et al., 2006; Cohen et al., 2000, 2002). Blocking means that firms write patents in a way so that they are close in nature to patents they already own and use for products, to prevent others from patenting them (Cohen et al., 2000). Blind et al. (2006) describe as defensive blocking as it assures freedom to operate. It may also imply that firms patent to prevent others from using a specific technology, a strategy labeled as *offensive blocking* by Blind et al. (2006). Both approaches mean that the inventions within the patents are not incorporated into products by the blocking patentee. This paper follows these definitions. Other reasons for patent protection that frequently play a role in pharmaceuticals are enhancing one's reputation and obtaining licensing revenues. Preventing lawsuits and using patents in negotiations play a minor role in this industry (Cohen et al., 2000).

3. Drug lifecycle management

The drug development and approval process in pharmaceuticals is long and costly, with only a few substances ever approved to enter the market (Girotra et al., 2007; Mathieu, 2005; PhRMA, 2007). At the same time, few blockbuster drugs provide exceptional returns. Pharmaceutical firms also try to identify synergies in R&D by seeking new medical applications for already developed drugs. This helps save time and costs in the lengthy approval process, as some preclinical tests for the substance can be reused from the previous approvals (Chong and Sullivan, 2007). For instance, Sandner and Ziegelbauer (2008) state that of all the drugs marketed in 2004 in the US, 84 percent had new medical indications approved,

[1] Patent thickets are found particularly in complex technologies such as electrical engineering, including semiconductors, telecommunications, but also optics (Cohen et al., 2000; von Graevenitz et al., 2008). Their existence has received much criticism, and there are various reasons for that. First, Heller and Eisenberg (1998) claim that such a situation would deter innovation and lead to the "tragedy of the anticommons," where resources such as patents are finally underutilized because of higher transaction costs. Second, the existence of thickets triggers firms to apply for even more patents (von Graevenitz et al., 2008; Ziedonis, 2004), expanding the anticommons dilemma and increasing workload at the patent offices. However, the large patent portfolios created in this context finally help improve the applicants' position in cross-licensing negotiations (Blind et al., 2006; Grindley and Teece, 1997) or facilitate membership in patent pools that altogether overcome hold-up problems here (Heller and Eisenberg, 1998; Shapiro, 2001).