The Development and Commercialization of Personalized Medicine Applications

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Introduction

Personalized Medicine (PM) - the tailoring of medical treatment to the patient's individual characteristics - holds great promise for the future of healthcare. Low drug efficacy and the occurrence of adverse drug reactions hamper the current paradigm of medicine, which relies mostly on a trial-and-error approach. Furthermore, the drug development industry is characterized by a high risk of failure, lengthy development cycles, huge investments and a declining R&D-productivity. Recent advancements in molecular biology have yielded a number of successful applications whereby knowing a patient's molecular or genetic make-up (also called a biomarker) enables to determine the best-fitting treatment. As such, this personalized medicine transforms the health care value chain in critical areas such as research and development, market access and health care provision.

Existing literature on personalized medicine mainly analyzes factors external to the firm such as payer coverage, regulation and access. However, little attention is paid to some of the main strategic issues faced by companies developing and commercializing personalized medicine applications. This paper addresses this research gap by investigating how and why drug developing companies access and integrate the (external) knowledge necessary for the development and marketing of these applications. The research question is formulated as follows: *What influences the propensity of drug developing companies to engage in strategic alliances when developing and commercializing personalized medicine applications?*

The aim of this paper is to build a theoretical framework on the strategic aspects of developing and commercializing a PM application. Firstly, we discuss PM and its impact on the development and commercialization strategies of pharmaceutical companies. Secondly, we present a comprehensive literature review on the knowledge-based view on the firm, the appropriability regime theory and the role of strategic alliances in the pharmaceutical industry. This allows for the exploration of the link between knowledge, intellectual property protection and future competition during the development and marketing of a PM application. Building on this literature, four expert interviews and several case studies, we build the proposed theoretical framework. It is proposed that the propensity to develop and market a personalized medicine application using strategic alliances and the nature of these alliances are influenced by the (1) the drug developing company's knowledge base on molecular diagnostics; and (2) the level of appropriability on the biomarker (in terms of IP protection and degree of novelty).

The results of this research may contribute to managers' and policy makers' understanding of how and why collaborations in the field of PM exist. Such knowledge allows for better decision-making processes on how to structure drug developing companies in a way that they can more easily tackle the many challenges in the field of Personalized Medicine.

Personalized Medicine

What is Personalized Medicine?

Historically, the response rates of patients to a major drug are low (Spear et a., 2001) and the burden of Adverse Drug Reactions (ADR) on public health and the health care system is high (Lazarou et al.,1998; Bates, 2010). Among other factors, genetic differences among patients are a major component of the non-preventable adverse drug events (Spear et al., 2001). Since patient populations are not as homogeneous as usually thought, there exists a need for more targeted therapies for smaller populations of patients. Until today, the pharmaceutical industry is still largely dependent on the model of blockbuster drugs[i] [ii] where 'one pill fits all patients'. However, the decreasing productivity of novel drug development urges the industry to develop new approaches and strategies, such as the development and commercialization of personalized medicine applications (OECD, 2011).

Personalized medicine (PM) - the right drug for the right patient - is the area of medicine using patient-specific information, called a biomarker, to better manage the disease, guide healthcare decisions and achieve superior medical outcomes. A biomarker is the biological indicator that predicts who will benefit from a particular targeted therapy (Abrahams et al., 2005; Sawyers, 2008; Davis et al., 2009; Trosman et al., 2010). Furthermore, biomarkers assist in the rational development of new therapies (Sawyers, 2008).

Some useful definitions

Therapeutic:	a drug or medicine.
Diagnostic:	a tool to identify or assess a condition or disease, e.g. tools used to monitor disease progression in HIV positive patients or screen the DNA of a patient for the presence of a specific genetic mutation.
Biomarker:	the biological indicator that enables health care professionals to predict which patient will benefit (or not suffer) from a particular therapeutic regime. These biomarkers are detected and monitored using diagnostic tools.

Personalized medicine thus refers to the ability to identify those patient subpopulations more susceptible to a particular disease or treatment. Interventions are then concentrated on those patients most likely to benefit from a certain treatment, avoiding ADR and other costs for non-responders (Davis et al., 2009; Bates, 2010;Trosman et al., 2010). Currently, there are 115 drugs approved by the US Food and Drug Administration (FDA) that include genomic information in the drug label. Of these, 22 drugs use a genetic marker to guide the use of the therapeutic. The latter class of Personalized Medicine Applications will be the focus of this research since they hold a direct link between the diagnostic (biomarker information) and the use of the therapeutic.

Companies developing a personalized medicine application face a number of economic and operational challenges such as defining and valuating the application field, establishing economic barriers and allocating the value between the therapeutic and its companion diagnostic (Trusheim et al., 2007; Davis et al., 2009).

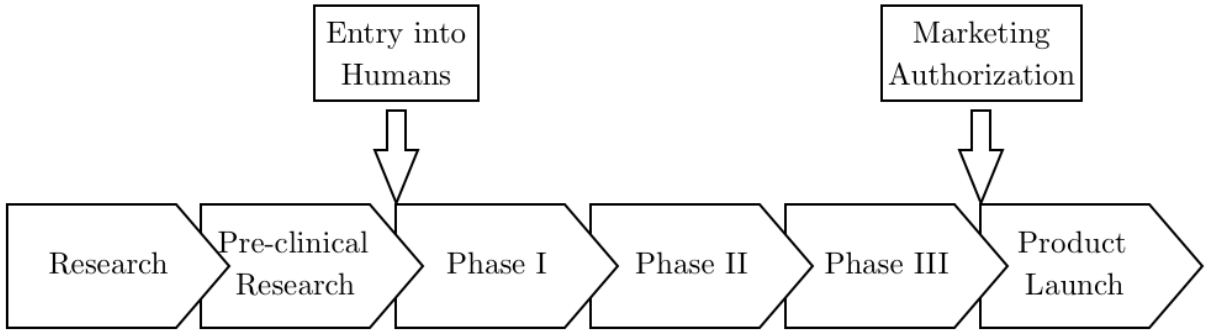
The Development of a Personalized Medicine Application

The drug life cycle is divided into two major parts: the phase during which drug development (pre-launch) takes place and the phase where the drug is on the market (post-launch), with the Marketing Authorization decision of the relevant regulatory bodies being the transition point.

The development of a new medicinal product follows a semi-standardized value chain and is presented in Figure 1. After the basic research and preclinical testing, candidate

compounds are then further tested on humans in three consecutive clinical phases. During these phase, an increasingly larger cohort of patients is enrolled with the aim of obtaining statistically significant data on the drug's efficacy before submitting the marketing authorization application.

Figure 1: The Drug Development Process. Own set-up.



The development of personalized medicine changes the expected time and costs of the development, revenues and product life as well as sales and market adoption costs of pharmaceuticals (Trusheim et al., 2007). In theory, the introduction of companion diagnostics improves R&D-productivity by decreasing clinical trial size, reducing drug development failure rates and/or lowering development time whilst augmenting market share and supporting higher drug prices (Cook et al., 2009; Davis et al., 2009; Brown, 2010). Extant literature discusses the required changes in the field of infrastructure, technology, regulation, reimbursement systems, strategies and business models in order to provide incentives for the various stakeholders of personalized medicine (Abrahams et al., 2005; Trusheim et al., 2007; Cook et al., 2009; Davis et al., 2009).

Strategic Alliances in the Pharmaceutical Industry

Introduction

The development of a new drug is characterized by a high risk of failure, lengthy development cycles and huge investments. Furthermore, the traditional pharmaceutical industry is faced with a declining R&D-productivity and an increased competitive pressure (DiMasi et al., 2003; DiMasi and Grabowski, 2007). This leads to a business model where early stage R&D is driven into the arms of young innovative drug developing companies (Willemstein et al., 2007) The importance of alliances in the pharmaceutical industry is therefore growing (Ernst & Young, 2011), strengthened by widespread option thinking (Grant and Baden-Fuller, 2004) and the presence of a complex and expanding knowledge base (Powell and Koput, 1996)

A number of possible strategic collaborations exist, ranging from loose collaboration at the low end to full acquisition at the high end, and from development over marketing (Kasch and Dowling, 2008). Kasch and Dowling (2008) find that both the resource-based view and the IP-rights theory contribute to a large extent to explaining commercialization strategies of young innovative biotechnology companies and thus collaboration in the life sciences industry. In this paper, we build on the knowledge-based view on the firm (which is a subset of the resource-based view) and the appropriability regime theory and apply them to the case of personalized medicine development and commercialization, however starting from an incumbent's point of view.

The Knowledge-Based View on Alliances

The resource-based view of the firm regards the firm as a bundle of tangible and intangible resources that are combined to direct and implement a firm's strategy (Wernerfelt, 1984; Barney, 1991; Priem and Butler, 2001; Newbert, 2007). In general, valuable, rare and hard-to-imitate resources combined with a good organizational structure (in terms of complementary assets and social structure) constitute the foundation of a sustained competitive advantage of the firm (Barney, 1991; Peng, 2009). The knowledge-based view on the firm regards knowledge as the most important resource of a firm and argues that the principal role of the firm is as an integrator of knowledge (Grant, 1996; Grant and Baden-Fuller, 2004).

Firms outperform markets in sharing and transferring knowledge (Kogut and Zander, 1992, Alavi and Leidner, 2001). Yet, production requires the application of multiple types of knowledge (Kogut and Zander, 1992), which are not always found within a single firm. Therefore, learning and innovation occur inside as well as outside the firm's boundaries (Cohen and Levinthal, 1990; Hitt et al., 2000). As such, access to and integration of external knowledge is key to an organization's success, especially in a knowledge-intensive industry, such as the drug development industry (De Clerq and Dimov, 2008).

The increasing role of external knowledge combined with the trend of firms focusing on core competencies spurs the formation of alliances as a formal vehicle to access or generate knowledge (Grant and Baden-Fuller, 2004).. Strategic alliances are inter-organizational collaborations situated between market transactions and acquisitions as two ends of the spectrum. They can take on many forms, yet generally, a distinction between equity-based and non-equity-based alliances is used (Peng, 2009).

In order for inter-organizational learning to occur, firms should possess absorptive capacity. Absorptive capacity is a firm's ability to recognize, exploit and utilize external knowledge for commercial ends and is critical to a firm's innovative capabilities This absorptive capacity is considered a function of the firm's prior knowledge (Cohen and Levinthal, 1990).

Now, what drives the propensity to form alliances with other firms? This propensity is influenced by the incongruity between the firm's product domain and its knowledge domain (Grant and Baden-Fuller, 2004). It is furthermore witnessed that an increased absorptive capacity, as a function of knowledge base, increases the firm's propensity to engage in alliances (Henderson and Cockburn, 1994; Mowery et al., 1996; Brusoni et al., 2001).

Firms use strategic alliances for either the exploration or the exploitation of external knowledge (Grant and Baden-Fuller, 2004; Lavie and Rosenkopf, 2006). If the main goal of the alliance is exploration, or knowledge generation, firms act as vehicles of learning. Exploitation, or access to knowledge, allows firms to leverage the other firm's (complementary) knowledge while remaining focused on the proprietary core competencies (Hamel, 1991; March, 1991; Grant and Baden-Fuller, 2004). The occurrence of both motivators as a driver for alliances is empirically witnessed (Mowery et al., 1996; Lavie and Rosenkopf, 2006). It has been argued that the focus in strategic alliances generally lies within accessing (exploiting) knowledge rather than generating (exploring) knowledge (Grant and Baden-Fuller, 2004). However, focusing on exploitation might imply that the partners involved have different long-term strategic goals, putting pressure on the relation in an alliance (Tidd and Izumimoto, 2002). Colombo, Grilli, and Piva (2006) argue that exploitative alliances are situated mainly in a commercialization setting while explorative alliances are mainly situated in the field of technology (development). The dichotomy should be viewed as a continuum in which firms balance exploration and exploitation within their alliances (Lavie and Rosenkopf, 2006).

The Appropriability Regime Theory

The appropriability regime theory finds that cooperation with incumbents is indispensable for entrepreneurial companies if the appropriability regime is tight, i.e. if strong intellectual property protection exists and future competition on the market will be high (Gans and Stern, 2003). If this is the case, cooperation will happen in order to access complementary assets owned by incumbents during the development and marketing of innovative products or technologies (Teece, 1986; Gans and Stern, 2003). At the basis of these dynamics, intellectual property (IP) rights play a key role in protecting the core assets of young start-ups and incumbents. Combined with the need for complementary assets during development and commercialization, collaboration seems a necessity rather than an option in the drug developing industry (Gans and Stern, 2003; Kasch and Dowling, 2008). Kasch and Dowling (2008) "find support for the general influence of the appropriability regime and the propensity to cooperate [in the biopharmaceutical industry, red.]"(Kasch and Dowling, 2008).

Conclusion

Strategic alliances are key in the drug developing industry. It is the aim of this paper to investigate how pharmaceutical companies are responding strategically to the new paradigm of personalized medicine and what influences their propensity to engage into strategic alliances. In order to do so, we construct a theoretical framework, drawing on the knowledge-based view of the firm and on the appropriability regime theory.

Research Question and Framework

Introduction

The following section will combine the theoretical backdrop, existing literature on personalized medicine, several case studies and the transcriptions of four expert interviews to formulate the research questions and to build the theoretical framework on the development and commercialization of personalized medicine applications by drug developing companies.

Research Question

Currently, a large number of drugs under development have an associated biomarker program (Ferrara, 2007; Aspinall and Hamermesh, 2007; Meckley and Neumann, 2010). Different types of knowledge are necessary to develop and market personalized medicine applications (Annie Hubert, personal communication, 17/11/2011). The fact that these are owned by several stakeholders (Verbiest, W., personal communication, 30/11/2011) such as diagnostic companies, biomarker discovery companies, drug development companies… makes that strategic alliances in which external knowledge is exploited and/or explored play an important role in this process. Whether a company will develop and market either therapeutics, or diagnostics, or both combined, is dependent, a.o., on the firm's own competencies (Trusheim et al., 2007; Brown, 2010). External factors may provide (dis)incentives for personalized medicine development companies (Abrahams et al., 2005; Aspinall and Hamermesh, 2007; Trusheim et al., 2007; Cook et al., 2009; Davis et al., 2009; Bates, 2010; Trosman et al., 2010).

We wish to explore the relationship between the firm’s knowledge base, its need for biomarkers and the strategic alliances which might be formed during the development and marketing of PM applications. We do this from a “drug developing company” point of view, which is any company engaged in the development and commercialization of therapeutics. Therefore, the research question addressed in this paper is: *What influences the propensity of drug developing companies to engage in strategic alliances when developing and commercializing personalized medicine applications?*

Aim of the Framework

We will look at answering this research question by combining the knowledge-based perspective and the appropriability regime theory in order to explore the link between knowledge on molecular diagnostics and (IP-)protection of the biomarker (which is often external to the drug developing form) during the development and marketing of PM applications. Looking at these aspects from the incumbent's (here the drug development company) point of view, we extend the commercialization theory and identify dominant strategies for drug developing companies.

As a premise, we regard the knowledge base of the drug developing companies in drug development as given and sufficient. It is proposed that two main factors influence drug developing companies' strategic alliances with biomarker companies during development and commercialization of personalized medicine applications: (1) *the drug development company's knowledge base on molecular diagnostics*; and (2) *the level of appropriability on the biomarker*. In the following subsection, we build the framework before summarizing the framework and discussing some implications.

The Development of the Framework

For the development of the framework we draw on the literature review, a number of personalized medicine application case studies and four expert interviews. The expert interviews were conducted in the fall of 2011 and included experts from several stakeholder groups in the process, namely academia, drug develping companies (with or without a diagnostics business unit) and diagnostic companies. The interviews were transcribed and are used in the following section to support statements on the development and commercialization of personalized medicine applications. An overview of the interviewees is presented in Table 1.

Table 1: Name, affiliation and stakeholder category of first round interviewees.

Name	Affiliation	Stakeholder Category
Rudy Dekeyser	VIB	Academic
Annie Hubert	Amgen	Drug Developing Company, limited Diagnostics Activity
Dirk Pollet	Multiplicom	Diagnostic Company
Werner Verbiest	Johnson&Johnson	Drug Developing Company, extended Diagnostics Activities

The molecular diagnostics knowledge base of the drug developing company

The development of a personalized medicine application requires a broad range of different knowledge types. This leads to increased marginal costs of knowledge integration while efficiency of integration is increased when using strategic alliances (Grant and Baden-Fuller, 2004). This model of mandatory collaboration is recognized by drug developing companies: "We should work more in partnership, we need access to tissue banks, we should collaborate with academics. We should collaborate more with the diagnostic industry, if we identify a biomarker, the test will have to be validated or even made specifically for our product. That is so complex [...]" (Hubert, A., personal communication 17/11/2011). Hence, drug developing companies employ a number of strategies: "Companies like Roche, Abbott and Johnson&Johnson have chosen a strategy to make a business in diagnostics. They

develop their medicines together with the companion diagnostics. Other firms, like Amgen, do not engage in the field of diagnostics." (Hubert, A., personal communication 17/11/2011) Within Johnson&Johnson, early detection and the availability of relevant diagnostic tools to improve medical outcomes is recognized to be key to obtaining long-term health care benefits while reducing healthcare costs. Therefore, the company acquired a number of specific assets (e.g. acquisition of the companies Tibotec-Virco, Veridex) and developed an in-house 'Companion Diagnostic Centre of Excellence' (Verbiest, W., personal communication, 30/11/2011). On the other side, key opinion leaders contact diagnostic companies to develop assays for selected biomarkers for use during the development of a therapeutic (Pollet, D., personal communication, 9/11/2012). These efforts point to the integration of external knowledge on molecular diagnostics in the drug development company's knowledge base.

Looking at two recently approved PM applications, Crizotinib and Vemurafenib[iii], we see a similar dynamic emerging:

- Crizotinib is used to treat selected patients with late-stage, non-small cell lung cancer and is commercialized in the U.S. by Pfizer. While Pfizer developed Crizotinib, it was Abbott that developed (in part) and commercialized the companion diagnostic for this drug[iv].
- Vemurafenib is used to treat selected patients with late-stage or unresectable melanoma and is developed and commercialized in the U.S. by Genentech, a subsidiary of Roche. The companion diagnostic is developed and commercialized by Roche Molecular, which is also part of Roche[v].

It is proposed in this study that the companies developing the PM applications (Pfizer and Genentech) needed access to knowledge on molecular diagnostics (from respectively Abbott and Roche Molecular). In the case of Crizotinib, this was found outside the organization, in the case of Vemurafenib it was found within the parent pharmaceutical concern. As such, the knowledge base and the absorptive capacity, as a function of knowledge base, of an organization appear to be the main drivers of strategic alliances during personalized medicine application development and commercialization. This leads to the formulation of our first proposition:

Proposition 1: The propensity of drug developing companies to engage in strategic alliances during the development and commercialization of a personalized medicine application is high if the drug developing company has a restricted knowledge base in the domain of molecular diagnostics.

Appropriability of the biomarker

We now turn to another important ingredient of successful development and commercialization of personalized medicine applications: the biomarker.

Many of the personalized medicine applications and associated diagnostics on the market are based on a limited number of intensively studied biomarkers. Discovery of these biomarkers occurred long ago, which makes that these biomarkers are considered part of the public domain (e.g. KRAS, Hubert, A., personal communication, 17/11/2011). Currently, only a handful of biomarkers are validated and thus useable in a development and commercial setting, despite enormous research efforts (Dekeyser, R., personal communication, 22/11/2011). It is one of the key challenges for personalized medicine: "But the big issue, it's the biomarkers... the validated biomarkers. How are we going to generate those validated biomarkers?" (Dekeyser, R., personal communication, 22/11/2011). As a result, it is a challenge for personalized medicine developing companies to access these (novel) biomarkers.

Currently, several companies are active in the discovery, development and validation of novel biomarkers, these companies : "[…] will have to collaborate closely with

pharmaceutical companies and academic centers." (Verbiest, W., personal communication, 30/11/2011). Biomarker discovery companies are struggeling with this model since it seems hard to validate a biomarker and the risk attributed to its (co-)development is high (Dekeyser, R., personal communication, 22/11/2011; Pollet, D., personal communication, 9/11/20122). This interdependence shows that, if the appropriability of the biomarker is high, meaning there exists a strong IP protection and the biomarker is relatively novel, collaboration between the drug development company and the (diagnostic) company owning the rights to the biomarker is inevitable. This leads to the formulation of our second proposition:

Proposition 2: If the appropriability on the biomarker is strong, the propensity of drug developing companies to engage in inter-firm collaborations during the development as well as during the marketing of the personalized medicine application is high.

However, the appropriability on biomarkers erodes quite quickly (Verbiest, W., personal communication, 30/11/2011) which leads to the rethinking of the biomarker business models (Dekeyser, R., personal communication, 22/11/2011). In case the appropriability regime on the biomarker is weak, the availability of diagnostic tools in the market is high, due to commoditization of technology and marker (Dekeyser, R., personal communication, 22/11/2011). In this case, whether or not alliances will occur during the development and commercialization will depend on the knowledge base on molecular diagnostics of the drug developming company. Indeed, if the company developing a personalized medicine application has access to knowledge concerning the biomarker, its absorptive capacity determines the need for strategic alliances. When Amgen launched Vectibix on the market, it chose not to develop and commercialize the companion diagnostic: "the diagnostic is done by third parties" (Hubert, A., personal communication, 17/11/2012). This was possible due to the widespread availability of laboratories being able to perform the diagnostic biomarker test. This leads to the formulation of the third proposition:

Proposition 3: If the appropriability on the biomarker is weak, the propensity of drug developing companies to engage in strategic alliances during the development will be influenced by its knowledge base while the propensity of drug developing companies to engage in strategic alliances during the commercialization phase is low.

Nature of the strategic alliances

In a final step, the drivers for strategic alliances formation in the field of personalized medicine are explored. Strategic alliances are used by firms for either the exploration or the exploitation of external knowledge (see supra). The aim of an explorative alliance is to expand the knowledge base of the drug developing company into the field of molecular diagnostics. On the other hand, the aim of exploitative alliances is to gain the rights to a particular biomarker. Therefore, the following propositions are formulated:

Proposition 4: Drug developing companies possessing a limited knowledge base on molecular diagnostics, when engaging in a strategic alliance to develop and commercialize a personalized medicine application, will engage in explorative alliances.

Proposition 5: Drug developing companies possessing a high knowledge base on molecular diagnostics, when engaging in a strategic alliance to develop and commercialize a personalized medicine application, will engage in exploitative alliances.

The Proposed Framework

Figure 2 summarizes the propositions by deriving the two main strategic questions faced by a company developing a personalized medicine application: (1) *What is the company's existing knowledge base on molecular diagnostics? (low/high)*; and (2) *What is the appropriability on the biomarker?(weak/strong)*.

Figure 2: A framework for the development and commercialization of personalized medicine applications

		Existing knowledge base on molecular diagnostics	
		low	high
Appropriability on the biomarker	weak	Development: Explorative strategic alliances	Development: In-house
		Commercialization: Market transactions	Commercialization: In-house or Market transactions
	strong	Explorative strategic alliances	Exploitative strategic alliances

Answering these questions leads to four dominant development and commercialization strategy outcomes for drug developing companies. These outcomes are discussed in the following paragraphs.

Existing knowledge base on molecular diagnostics is low, appropriability on the biomarker is weak.

The PM application developing company will engage in explorative strategic alliances during the development phase. Strategic alliances will be scarce in the marketing phase due to the commoditization and presence of the diagnostic biomarker tests.

Existing knowledge base on molecular diagnostics is low, appropriability on the biomarker is strong.

The PM application developing company will engage in explorative strategic alliances during the development and commercialization phase.

Existing knowledge base on molecular diagnostics is high, appropriability on the biomarker is weak.

In this case, the PM application developing company will develop the application in-house. The commercialization strategy is influenced by the company's ability to obtain competitive advantage in the diagnostics market. In case this proves difficult, the diagnostic is left to the market, in case it is attainable, these drug developing companies might engage in the related diagnostic business.

Existing knowledge base on molecular diagnostics is high, appropriability on the biomarker is strong.

The drug developing company will engage in exploitative strategic alliances during development and marketing phase, since it has limited incentives to expand its knowledge base on molecular diagnostics but rather strives for access to the biomarker and permission to use this knowledge in the development and commercialization stages.

Conclusions

Personalized Medicine (PM) holds great promise for the future of healthcare. Existing

literature on personalized medicine mainly analyzes factors external to the firm. It is the aim of this paper to address the main strategic issues faced by companies developing and commercializing personalized medicine applications. Therefore, we investigate how and why drug-developing companies access and integrate the (external) knowledge necessary for the development and marketing of PM applications.

After introducing personalized medicine, we present a short overview on the knowledge-based view on the firm and on the appropriability regime theory. We combine this theoretical backdrop, several case studies and the results of expert interviews to explore the relationship between the firm's knowledge base, its need for biomarkers and its strategic alliances during the development and marketing of personalized medicine applications. Therefore, the research question addressed in this paper is: *What influences the propensity of drug developing companies to engage in strategic alliances when developing and commercializing personalized medicine applications?*

This paper thus explores some of the key questions regarding strategic alliances in the field of personalized medicine. It is proposed that two main factors influence drug developing companies' strategic alliances with biomarker companies during development and commercialization of personalized medicine applications: (1) the proprietary knowledge base on molecular diagnostics; and (2) the level of appropriability on the biomarker. We construct a number of propositions on the relation of strategic alliances in the field of personalized medicine with both of these factors as well as with the drivers underlying these strategic alliances.

The framework summarizes the propositions and allows for deriving four dominant development and commercialization strategies for drug developing companies. If the appropriability on the biomarker is strong, strategic alliance formation is driven by the need to access to the biomarker, yet the nature of the alliance is determined by the firm's knowledge base in molecular diagnostics. When the appropriability on the biomarker is low – which is a matter of time – the drug developing company's knowledge base will drive strategic alliance formation during development while the effect on commercialization strategy is determined by the firm's ability to retain a competitive advantage on the diagnostic market.

International and Managerial Implications

The framework presented in this paper allows for the visualization of the dominant development and commercialization strategies of drug developing companies in the personalized medicine field. Starting from the firm's proprietary knowledge base on molecular diagnostics and the appropriability regime of the biomarker, it provides managers with a framework to position their company and develop strategies to access or acquire necessary knowledge. Furthermore, this framework assists in unveiling the drivers of strategic alliances between drug developing and/or biomarker companies. The framework also allows for studying current strategic alliances and their future evolution. As such, a better alliance planning and management can be achieved. For instance, during the I-SPY 2 clinical trial[vi] , several drug developing companies, possessing divergent knowledge bases on molecular diagnostics, test their therapeutics in relation with a number of common (weak appropriability) and novel (strong appropriability) biomarkers. Our framework assists in assessing the future collaboration scenarios that might occur depending on the trial outcomes. The framework also assists in assessing proprietary and competition's strategy under pressure of the eroding appropriability on the biomarker and expected commoditization of diagnostic tests.

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Endnotes

[i] A blockbuster drug is a drug which generates sales of more than USD 1 billion per year.

[ii] In 2011, the top-200 best selling drugs in the U.S. sold for over 124 billion USD, with the top 10 blockbuster drugs accounting for 30 percent of this total. The top-25 of best selling drugs account for 50% of the total revenue (Data from www.drugs.com [website accessed on 02/04/2012]).

[iii] Data retrieved from http://www.fda.gov [website accessed on 28/03/2012].

[iv] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm269856.htm [website accessed on 02/04/2012].

[v] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm268241.htm [website accessed on 02/04/2012]

[vi] Data retrieved from http://www.clinicaltrials.gov and http://www.ispy2.org [websites accessed on 03/07/2012]