

Internationalization of Molecular Medicine Companies: GenoMed's Case Study

Pedro Falcato Velez
Técnico Lisboa / UTL, Lisbon, Portugal
pedrofvelez@ist.utl.pt

Abstract — An increasingly global marketplace, combined with a deep internal economic crisis, forced Portuguese technologic firms to turn into foreign countries to maintain its competitiveness. For a small enterprise, an international expansion needs to be carefully planned, being the objective of this research to develop an internationalization strategy for GenoMed, a Portuguese molecular diagnostics firm, generalizing from this case study an approach which could stand as a framework for small Portuguese molecular diagnostics companies' internationalization process.

The existing literature on distinct pattern models for firms internationalization is revisited, from economic approaches to the most recent “born-global” and “born-global again” firms. Moreover, the factors which influence the internationalization process and the different market entry modes used by firms are reviewed.

A case study approach was used as research methodology, providing the structure to develop an extensive analysis of the molecular diagnostics industry, its market and an internal analysis of GenoMed, to evaluate its current strategy and competitive position in the marketplace.

According to the developed research, GenoMed should pursue a competitive advantage through differentiation, aiming the narrow niche market of molecular diagnostics. Its international competing approach should be global, however differentiating the strategic objective in three different segments: Eastern-Europe countries, where partnerships should be pursued for testing outsourcing (to GenoMed), fast growing economies like China and Brazil, where alliances should aim for crossed-shareholding and licensing, and the rest of the world, where GenoMed should improve its international network and develop an image of high quality laboratory for rare diseases diagnostics.

Index Terms— GenoMed, molecular diagnostics, case-study, internationalization, high-tech firms, strategy

I. INTRODUCTION

An increasingly globalization of the marketplaces, combined with an internal economic crisis, forced Portuguese

technologic firms to turn into foreign countries in order to increase revenues and continue to be competitive. This internationalization needs to be carefully planned and follows very clear objectives: broadening its clients' portfolio, so small firms become less dependent of specific buyers, therefore spreading the risk on more than one country, and to use its home market-leadership abroad to increase its sources of revenue. The objective of this research is to develop an internationalization strategy for GenoMed, a Portuguese molecular diagnostics firm.

Existing literature deeply strengthens the necessity of a pre-internationalization phase during which firms develop an entrepreneurial motivation into the international expansion and a solid network of contacts across foreign countries, together with an improvement of its marketing and international knowledge.

Two distinct internationalization pattern models arise in the literature: economic approach, based in the natural development of internal competitive advantage into an exportation phase, and a behavioral approach, where firms develop a dynamic attitude towards internationalization, by increasing firms international commitment in an incremental evolution. However, none of these schools of thought about international operation was able to describe an increasingly global phenomenon: the “born-global” or “born-again global” enterprises. These firms try to enter the international marketplace since its inception, or in a specific timeframe, in order to make the most of its competitive advantage. This internationalization pattern is especially relevant in fast-paced industries like health and high-technology, where products life cycle and its commercialization window is, usually, much narrowed. The different possibilities for entering foreign markets, as well as its advantages and disadvantages, are also analyzed.

Molecular diagnostics industry and internal GenoMed's analysis were performed, through a case study methodology. The most important sources of information were structured interviews and documentation analysis. From this study, it was possible to assess the great potentiality of this industry, which is developing at a huge pace, as well as some perks hampering its growth, like regulatory, legal and political hurdles, combined with economic times of crisis, which lowers the needed investment to further develop its technologies and prove its clinical validity. With the conclusions obtained in the industry and firm analysis, it was possible to develop a strategy for this company.

According to the developed research, GenoMed should pursue a competitive advantage through differentiation, aiming to the

narrow niche market of molecular diagnostics. Its international competing approach should be global, however differentiating the strategic aim for three different scenarios: Eastern-Europe countries, where partnerships should be pursued for testing outsourcing to the Portuguese laboratory, fast growing economies like China and Brazil, where alliances should aim for crossed-shareholding and licensing, being GenoMed responsible for scientific knowledge and technical know-how introduction, and rest of the world, where the firm should improve its international network and develop an image of high quality laboratory for rare diseases diagnostics.

II. STATE OF THE ART

A. Introduction

Internationalization can be defined, in a literal meaning, as making something international (Oxford Dictionaries 2010). In the business world however, the definition is explained as “*a sequential and orderly process in which firms gradually increase their international involvement*” (Johanson & Vahlne 1977).

The factors leading firms to pursue their internationalization process are often diverse. According to (Thompson et al. 2012), this strategic move may pursue the enlargement of the target market, the achievement of lower costs through economies of scale, to expand home-market leadership and to spread the risk across a wider market base.

Competing in different countries of the world is naturally more difficult and complex than home market competition only. Several issues may take a part in this higher market complexity, being the unpredictability of industry's competitiveness and differences in governments' policies and economies some examples.

This arise in complexity reinforce the importance of strategic planning in the analysis of firms current situation, possible benefits with internationalization and the definition of how this objective is going to be achieved, since “*the better conceived a company's strategy and the more competently it is executed, the more likely that the company will be a standout performer in the marketplace*” (Thompson et al. 2012).

B. Factors that lead towards internationalization

As suggested by Welch (1977), in (Tan et al. 2007), to understand why and how an internationalization orientation begins within a firm, the decision-making process and factors that impact it need to be explored.

The most relevant factors, according to (Tan et al. 2007) that push a firm into international expansion are internal and external stimuli, the psychological commitment and resources of the firm, as well as the lateral rigidity within firm's elements.

Internal stimuli, like interested managers with required market experience and strong network, have the potential to present opportunities and encourage international consideration.

Regarding external stimuli, factors as foreign demand and its impact on scale economies achievement and relative factor costs, government supports and competitive pressures in domestic markets, may also lead firms into internationalization.

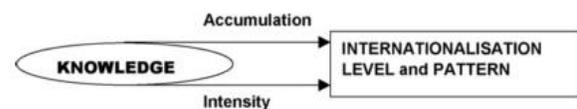
To a correct employment of these informational inputs and opportunities exploitation on internationalization decision, it is necessary a previous learning process. Therefore, only when sufficient information pointing towards international expansion has been assimilated and translated into usable knowledge and resources required are gathered, a firm is ready to move abroad.

The psychological commitment triggers the decision-maker to research more information and evaluate opportunities related to foreign markets, therefore opening the possibility for resources allocation to internationalize.

The available resources of a company will also influence decision-makers about firm's readiness to internationalization, as they play an important role in its long-term sustainable competitive advantage. Lateral rigidity is capacity of the decision-maker to perceive stimuli factors and the existing resources within the firm.

C. Role of Knowledge

During the internationalization process of firms, the accumulation of experimental knowledge is one of the most important factors that positively stimulate the rate of expansion. In small firms that are international from inception, the existing lack of experimental knowledge can usually be replaced through knowledge acquisition and prior management learning, hiring already experienced professionals to their managerial team. In a high technology, knowledge-based market, different types of knowledge and their intensity emerge as preponderant to firms' international success (Brennan & Garvey 2009). The accumulation of knowledge through high levels of R&D (technological knowledge) and hiring individuals with prior international experience (international knowledge) will leverage the internationalization pace and pattern in a positive relation.



These relations are illustrated in Figure 1.
Figure 1 - The role of knowledge in firms internationalization (Brennan & Garvey 2009).

Three different types of knowledge can be considered as preponderant in an internationalization process: technological knowledge (about firm's products and production), international knowledge (on international business conduction) and marketing knowledge (in order to take advantage quicker, since shorter products life cycle are expected in this industry).

D. Pre-internationalization phase

Pre-internationalization phase may be defined as “*a state all firms experience before their initial commitment to a foreign market*” (Tan et al. 2007) and a model positioning it in internationalization pattern can be created.

According to (Styles & Genua 2008), in firms created through the commercialization of university-developed technology, precise internationalization models could be constructed,

being strongly influenced by the managerial pattern of behavior, entrepreneurial orientation and international networks.

One first step replicated through both companies, was the decision to hire someone with managerial background as CEO of their team, with intention to complement the technological knowledge they already have and to smooth the interaction with business world (Styles & Genua 2008). The industry recognition and interest also proved to be preponderant in credibility built up, improving negotiation power near investors, a fundamental factor within born global start-ups financing difficulties.

As nowadays companies live in an era of information and knowledge intensive industries, collaboration between firms has become mandatory, with fragmented ownerships and partnerships between firms being one of the most common solutions to increasingly competitive marketplace (Mcgee & Bonnici 2002). To respond to this industry frame, a strong network is likely to allow a better firm performance.

Regarding an entrepreneurial focus, it was possible to confirm a need for the existence of a product champion, openness to innovation and the adaptation of product strategy and proactiveness in problems foreseen.

E. Internationalization pattern model: born-global paradigm

Today's world economy is globalizing at an accelerating pace and, as geographical distance becomes less important due to all the advances in information technology and communication and as historically closed borders open their markets to foreign companies, new opportunities and threats start to drive ambitious firms to compete in the global market faster (Thompson et al. 2012).

Under these circumstances, firms begin to internationalize in a very early stage of development, sometimes from inception, with especial impact in advanced technology industries (Oviatt & McDougall 1994). For these reasons, a relatively new phenomenon is attracting attentions of international research – “born global” firms – being this concept worth of attention and hence explored, together with a relatively new companies' concept: the “born-again global” firms. These enterprises are forced to reinvent themselves in the international picture due to low internal demand for their products.

According to (UNIDO 2006), the survey showed that two main type of exporters could be identified: (1) firms that built a solid base in domestic-market over the years and used exportation as a strategy of grow following the traditional patten of internationalization of MNEs; and (2) firms, normally SMEs, that are export oriented from inception, being the world their marketplace and using home market as a support for an international business – the born-global or born-again global firms.

(Oviatt & McDougall 1994), in (Rasmussen & Madsen 2002), defined four different types of International New Ventures (INVs), regarding the number of countries involved and the coordination of activities of value-chain across countries: export/import start-ups, multinational traders, geographically-focused start-ups and global start-ups. The different typologies of INVs are represented in figure 2:

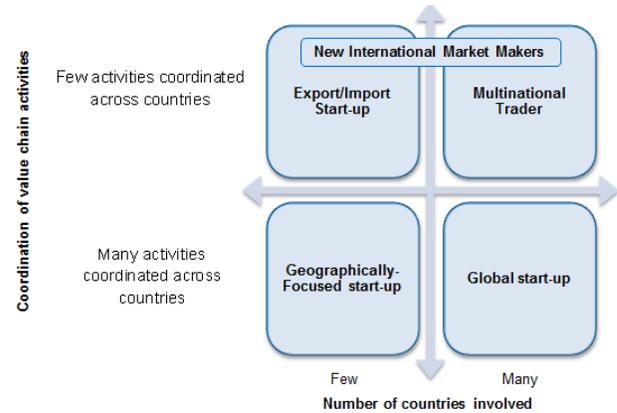


Figure 2 - Types of International New Ventures ((Oviatt & McDougall, 1994), in (Rasmussen & Madsen 2002)).

The model proposed attributes the quest for international market motivation to a more committed management, trying to conquer “global niches” on a proactive attitude. This global market strategy has the objective of gaining “first mover” advantage, achieving rapid penetration of the desired market segment, therefore locking-in clients and protecting proprietary knowledge. This fast-paced global market penetration is especially important on high-technological industries, where products tend to have shorter life cycles, with constricted windows of commercial opportunity.

To born global firms, the international expansion is normally concurrent, even sometimes precedent, to home market establishment. Companies born global tend to have diversified and flexible entry modes in the global market. Exportation, licensing agreements, joint ventures and alliances with costumers and/or suppliers are the most common methods to penetrate the selected markets.

The internationalization process tend, as it is possible to perceive, to adopt a very structured and planned approach, in contrary to traditional pathways, much more reactive to markets opportunities and risk aversion (Bell 2003).

F. International market entry modes

According to (Thompson et al. 2012) when a firm decides to expand internationally, a strategic decision must be made on choosing the entry mode that best suits each specific foreign market. The decision on which entry mode to apply will depend on a variety of factors, but generally higher levels of investment and risk offer superior revenues and control. Therefore, when entering an international market, firms tend to adopt a risk crescent internationalization pattern, which allows learning through the process and built trust and confidence.

Exporting activities are the most common enter strategy into foreign markets due to its low risk character and low investment requirements, being domestic production used as a base for exporting products to external markets.

The second entry mode firms tend to adopt to start their internationalization process is through licensing, used when a firm owns a valuable patent, technical know-how or an appealing brand, but doesn't have the necessary resources or organizational capability to enter a foreign market on its own (Thompson et al. 2012).

The third entry mode used by firms to go international is franchising, a strategy similar to licensing but best suited to service enterprises (Thompson et al. 2012). In franchising, the contract attributes the responsibility, risks and costs of construction in the foreign country to the franchisee and the administration costs related with recruitment, training, support and monitoring to the franchisor. The franchisee is also responsible for a fee payment to the franchisor.

The fourth entry mode often used by firms to move abroad is strategic alliance or joint venture (Thompson et al. 2012). Companies internationally expanding tend to form partnership with a foreign company to share the ownership and control of the firm (Kotler 1994) and is mostly used when the internationalizing firm has limited resources (venture might require high investment), wants to share risks, lacks market knowledge or needs to satisfy this requirement from the host country's government (specially frequent in less developed countries) (Thompson et al. 2012). According to (UNIDO 2006) equity alliances can be defined as a form of collaborative agreement where at least one of the collaborative companies assumes ownership position in the other company, for example by shares buying or swapping. Joint ventures should be understood as a long-term participation of two or more firms in a new enterprise (usually a new legal entity) in which each company participates as owner, contributes with assets and shares part of the risk.

An acquisition is a combination in which the acquirer firm purchases and absorbs the operations of the acquired one, therefore closing its activity. This is, however, an expensive ownership option.

The last entry mode a firm can use to go international is a Greenfield venture, which is also an ownership option, by creating a new subsidiary business in the selected foreign market, setting up the entire organization from the ground up (Thompson et al. 2012).

III. METHODOLOGY

A. Research Method

Since this investigation was conducted as an exploratory research, where no control over behavioral events was possible and where its main focus were contemporary events, the case study methodology represents the most adequate approach to employ.

A case study was defined by Schramm (1971) as: *“The essence of a case study... tries to illuminate a decision or set of decisions: why they were taken, how they were implemented, and with what result”* (Yin 2009, p.17).

The scope of this research being the development of an internationalization plan for one enterprise, it was necessary to choose between a single case study approach, which offers an in-depth analysis of one organization, and multiple case-studies, offering ground basis for theoretical generalization. The single case study was used, a needed trade-off so a complete study about the organization's characteristics is created to support the strategic plan to its internationalization process.

B. Research quality

The data used in this research was obtained through semi-structured interviews with different elements of the firm, together with documentation and archival records analysis.

To ensure the validity and reliability of the collected information, interviews followed a previously created protocol and were conducted in separate to avoid peer pressure biases. Top managers were interviewed, so the information given is more close to the reality because they are not afraid to give their truth opinion and drafts were sent for interviewees' revision for validation.

The generalization was based in the theoretical framework and existing studies about the entire industry.

IV. CASE STUDY ANALYSIS: GENOMED, S.A.

A. Introduction

1) *GenoMed - Diagnósticos de Medicina Molecular, S.A.*

GenoMed - Diagnósticos de Medicina Molecular, S.A. is a spin-off company of Instituto de Medicina Molecular (IMM), located in the campus of Faculdade de Medicina da Universidade de Lisboa (FMUL) and Hospital de Santa Maria (HSM), and its prime offer are diagnostic services in the Molecular Medicine field.

The firm was created in October of 2004 by the vision of Professora Carmo Fonseca. The mission of GenoMed is to provide the transfer of scientific knowledge in the field of Molecular Medicine into clinical practice. For that purpose, the molecular genetics services provided are complemented with a R&D unit that cooperates with clinicians, researchers and industry, for disease diagnostics and innovative product/tests development.

The enterprise main sources of revenue are molecular genetic tests. In addition to the genetic diagnostic tests and oncology, GenoMed additionally runs parental and ancestry DNA testing, DNA profiling and genealogy studies.

Nowadays, GenoMed is composed a multidisciplinary team, and its structure is divided in two main areas: genetic and pharmacogenetic diseases, composed by clinical and non-clinical tests, and oncology, composed by cytogenetics, hemato-oncology and solid tumors analysis.

Inside genetic and pharmacogenetic diseases clinical tests, several medical specialties are covered: hepatology, cardiology, urology, hematology or pharmacogenetics, among others, in more than 350 different molecular tests.

GenoMed is licensed by the Direção Geral de Saúde since 2007 (License number 0075L/2007) for Genetics and Molecular Pathology and certified for quality management according to the standard NP EN ISO 9001:2008 (2009/CEP.3390).

2) *Molecular Diagnostics*

Molecular is nowadays considered as an area of diagnostics undergoing one of the most dynamic and transformative changes (AdvaMedDx 2013). The advances in research, diagnostics and treatment are already causing huge impact in health care, leading to a promise of revolution in medicine.

The ability to deliver effective health care depends on the ability of the health care provider to accurately identify the cause of the patient's problem or, in other words, to make the

right diagnostic. Therefore, it is possible to assume that the foundation of a successful health system are the diagnostic tests, by providing objective, quantitative measurements that assist and inform on every stage of health care, from prevention to treatment.

According to (AdvaMedDx 2013), the term “*molecular diagnostics*” embraces a class of diagnostic tests that assess the health of one individual at molecular level by detection and measurement of proteins or specific genetic sequences responsible by those proteins synthesis, in deoxyribonucleic acid (DNA) or ribonucleic acid (RNA).

3) *Technology of molecular diagnostics: Genetics*

In the late years, a great revolution and development pushed genetics to the highlights of medicine, giving arise to promising areas such as gene therapy, genetic engineering, diseases diagnostics and personalized treatments (World Medical Association 2009).

Genetics, as a field in medicine, can be defined as the study of every aspect of genes, the fundamental units of biological information, composed by molecules of deoxyribonucleic acid (DNA). Genetics might be separated into two fields of research: the molecular genetics, which study genes into deep, therefore only dealing with few at a time, and genomics, which study sets of genes as a whole (genomes).

Although DNA structure is able to replicate itself to ensure the persistence of its information through time, it allows for mutations, in which random changes occur during the process of replication. These mutations are in fact the source of the great diversity and evolution of life, being acted on by natural selection over time and giving rise to new species. However, these mutations can also cause diseases and malfunctions.

Therefore, the study of this field is of tremendous interest, especially since the technological evolution have allowed, through a series of methodologies and techniques, to isolate, study, understand and compare individual genes and genomes and how the function is normal and disease organisms (Griffiths et al. 2012).

The future is bright for genetics and its applications in biotechnology, which are developing in a much faster pace than public policies, laws and social conventions. However, as all technological revolution, they give rise to not only medical, but also social, ethical and legal implications and concerns that need to be publicly discussed and explained, so a genetics-related sensitivity is developed in general public (World Medical Association 2009).

The most important techniques used in molecular diagnostics are the polymerase chain reaction (PCR), which is a rapid cell-free DNA cloning technique created during the 1980s which makes use of purified DNA polymerases to replicate specific DNA sequences. This method is quick, highly sensitive and robust, being widely used for DNA amplification and quantification of both DNA and RNA (Strachan & Read 2010) (Griffiths et al. 2012).

After the target DNA is amplified it is necessary, in order characterize it at a molecular level, to discover the nucleotide sequence. To do so, the most commonly used method and still routine at almost every lab in the world was developed by Fred Sanger, is known as dideoxynucleotide chain-termination

sequencing or Sanger sequencing and gave him and Walter Gilbert the Nobel Prize in 1980 (Klug et al. 2012).

Compelled by relatively high costs and not high enough output for the growing demand of sequencing data (Klug et al. 2012), new sequencers that are faster, capable of generating millions of bases of DNA sequences in a quick method were needed, which led to the development of NGS approaches. These NGS techniques process various reactions simultaneously, using state-of-the-art imaging techniques and generating large volume of DNA sequence data almost 200 times faster than before and for much lower prices.

Although several methodologies and technologies were developed for genetic sequencing in the last years, Illumina (mainly due to cost-effectiveness factors) and Ion Torrent (data throughput/time per run and low overall error rate) assumed leading roles in this field (Morozova & Marra 2008) (Xuan et al. 2013).

The Illumina technology, based in sequencing-by-synthesis chemistry, uses reversible terminator nucleotides for the four bases, each one labeled with distinct fluorescent dye (Ansorge 2009) and Ion Torrent uses a semiconductor chip capable of translating chemical signals (drop in the solution pH due to proton release when a nucleotide is incorporated) into digital information (potential difference production).

B. *Market Definition*

According to (Goverman et al. 2012), molecular diagnostic products or services use specialized research technology with proved relevant therapeutic effect, applying it to a clinical laboratory activity. The market of *in vitro* diagnostics is becoming one of the most important players in the healthcare provision and patient care quality, by providing approximately 80% of the information physicians use to make medical decisions. Nowadays, clinical laboratories have managed to develop competencies and means to be capable of diagnosing a wide variety of diseases, from different fields such as immunology, cardiovascular or oncology.

1) *Market Segmentation*

According to (AdvaMedDx 2013), molecular diagnostics is a relatively small portion of the overall diagnostics market, consisting only in 11% of the overall size. However, it is its fastest growing segment. What once was a specific market by its own is now part of the big market of clinical analysis and *in vitro* diagnostics (IVD) due to the gradual standardization of the test through commercial kits developed by the most important players of the field and by the emerging interest the genetics as a medical specialty is receiving.

The genetic tests then become a specialized niche inside clinical diagnostic analysis industry, being this integration reinforced by the present evolution of the market, since NGS techniques will neglect the need for specialized human resources, standardizing even more the prices of the tests.

Operating in the specific niche of genetic tests market, the main rival firms of GenoMed are:

- Centro de Genética Clínica (CGC), which is based in Oporto and has a small sample collection lab in Lisbon, but operates in the entire country;

- Instituto de Patologia e Imunologia Molecular da Universidade do Porto (IPATIMUP), with main focus in the North region but with operations in the entire country;
- Genética Médica e Diagnóstico Pré-Natal (GDPN), belonging to General Lab group, this company is based in Oporto and its activity is more focused in the north region, although it operates in the entire country;
- Instituto de Biologia Molecular e Celular da Universidade do Porto (IBMC), Faculdade de Medicina da Universidade do Porto (FMUP) and Instituto Nacional de Saúde Dr. Ricardo Jorge (INSA), mainly operating in the north and center of Portugal, but with low relevance in the overall industry.

2) *Buying decision criteria*

For physicians, the principal requestors of genetic tests, the most important buying decision criteria are:

- Lower prices, imposed by Hospitals Management;
- Quality and reputation of the laboratory;
- Quickness of answering;
- Previous relationship with laboratories and capacity to communicate (allowing for personalized treatment);
- Localization of the laboratory (which needs to be close);
- Trustworthiness of the laboratory, with low or non-outsourced tests.

The factors enumerated above, according to the interviewed people from GenoMed, are homogeneous in developed countries, with exception of price, which loses importance in countries with more stable and rich economies.

C. *External Environment Analysis*

1) *Macro-Environment: PESTL Analysis*

Every company operates within an industry, which is part of a bigger scale environment, which will influence the company's immediate reality. Therefore, the most important issues found to influence molecular diagnostics industry are:

- In the political and regulatory field, the lack of regulatory frame is persistently forgotten in the healthcare political measures, which prejudice molecular diagnostics development;
- For legal and ethical aspects, the need for informed consent signing in health individuals' tests and the ethical concerns the genetics field arise are hampering the establishment and development of the field;
- For economy, the most important factors are the intense crisis affecting the country, which caused payments by public hospitals to severally drop and a decrease in demand;
- By social subjects, it is important to highlight the increasing comprehension of the field by general public and by a new breed of aware clinicians, which contributes to the incorporation on daily practice and to decrease the concerns around this recent field of medicine;
- On the technology plane, the incorporation of knowledge of molecular genome to prove clinical practice utility and better diagnose ill patients, as well as predict future diseases in health people and the uprising usage and clinical application of NGS technologies will contribute to revolutionize this industry in a 5 years period;
- Finally, the changes in the country's and world's demography, with increasing life expectancy and low birth rate of developed countries, contributes to the increase of the

elder population, one of the important target population of molecular testing due to the development of chronic diseases.

2) *Industry's Dynamics Analysis*

According to (Raskin & Casdin 2011), a team responsible for identifying secular changes in the drivers of economic or industry growth, a game-shift disruption is beginning to occur in the healthcare industry. These changes will have implications in drug research and development and in diseases diagnosis and treatment, with repercussions across every stage of healthcare and technology sector.

The most important drivers of change are the increase of life expectancy in the world (Raskin & Casdin 2011) (Prweb 2013), the development of the scientific and molecular processes involved in specific diseases knowledge, the technological development of NGS and biomarkers, the establishment of greater clinical relevance of molecular tests and, on the down side, the economic crisis affecting Portugal.

As impacts of the indicated drivers of change, it will be possible to observe an accentuated increase in life expectancy and chronic diseases prevalence, driven by the incorporation of molecular tests in healthcare practice, and the exponential development of this field of medicine as its clinical validity is proved and more investment is made.

In the developing countries, market growth is being propelled mainly by growing population access to healthcare and significant government investments for healthcare development, in contrast with developed countries where market's growth is being restrained by economic restrains, regulatory and ethical issues and evidence expectations from payers, either governments from European countries where public healthcare systems exist or insurance companies (AdvaMedDx 2013).

According to several studies, an average growth of about 7% for IVD and about 15% for molecular diagnostic tests is expected for these markets, with the infectious diseases and oncology testing, together with new emerging markets, leading this growth (Raskin & Casdin 2011; Prweb 2013; AdvaMedDx 2013). The expected revenue and penetration of molecular diagnostic tests is expected to grow quickly, from \$4.4 billion in 2010 and about 11% market penetration to \$21 billion and around 80% of market penetration by 2020. This will represent an increase from about 11% of global \$40 billion IVD industry to about 31% of an estimated \$67 billion industry by 2020 (Raskin & Casdin 2011).

3) *Market Attractiveness: Porter's Five-Forces Model of Competition*

The Porter's five-forces model of competition takes into account five different forces which directly influence industry's profitability through different competitive pressures: rival companies, potential new entrants to the industry, competition from firms producing substitute products and supplier and customer bargain powers.

This analysis allowed the construction of a radar-graph representation of the industry's attractiveness, which is represented in figure 3, with the specific rank attributed to each competitive pressure.

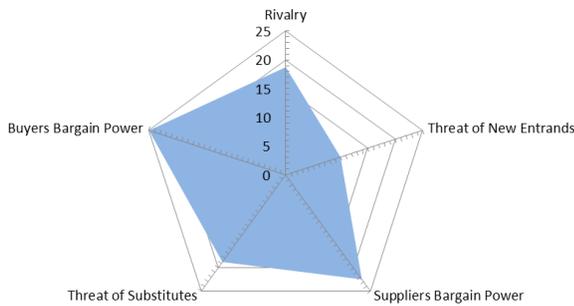


Figure 3 - Radar-Graph representation of Porter's Five forces Model for industries attractiveness.

The average rank obtained was 19.25, or 77% of the 25 total points, which indicates the overall unattractiveness of this industry. The great part of the forces were ranked high, with exception for the threat of new entrants, which might be an outcome of the high competition existing among rival firms and low bargain power of industry's players when negotiating with either suppliers or buyers.

D. Internal Environment Analysis

The value chain of a company represents a collection of all the activities performed internally, from the designing and production of the product to the marketing, delivering and product's supporting activities and its main objective is to examine all the value-creating activities.

As primary activities of the firm's value chain, biological samples received in GenoMed are identified and catalogued, passing afterwards through the required treatments in the firm's laboratories in order to produce the final report where an analysis is performed before it is sent to clinicians. On marketing and sales actions, it is important to highlight a recent rebranding and website creation, together with promotional kits and advertising in industry's conferences.

For the support activities, human resources receive regular training and entrance formation, along with rigorous staffing through competence matrixes usage. On technological development, important investments are being done in NGS adoption and diagnostic tests designing as response to clinicians' request.

Mainly due to the economic crisis affecting the country and the deep connection and dependence on Centro Hospitalar Lisboa Norte, which lowered tests requirement and internalized certain areas of tests, GenoMed's financial health decreased. However, actions towards broadening of the clients' portfolio minimized this trend when comparing to previous years.

An analysis of the company's resources and capabilities revealed biomarkers testing kits and Next-Generation Sequencing equipment operation, Instituto de Medicina Molecular, organizational culture and in-house development of methodologies as the most important competitive and sustainable advantages within the firm.

E. Company's Competitive Position Analysis

1) Key Success Factors

For the molecular diagnostics testing industry, according to the interviewees, the most important factors firms need to

concern are pricing competitiveness, quality of the offered services, clients loyalty, human resources formation, the existing scientific knowledge and the research and development performed in the firm.

2) Benchmarking

It is utterly important to understand not only how competitively strong a company is against its key rivals, but also how does the company rank relative to competitors on each KSF, in order to have an overall evaluation of firm's competitiveness through a weighted competitive strength assessment, represented in Table 1.

Table 1 – Weighted competitive strength assessment. Rating Scale ranges from 1 (very weak) to 20 (very strong).

KSF	Competitive Strength Assessment (Weighted Score)				
	GenoMed	CGC	IPATIMUP	GDPN	IBMC
Price	2.34	2.88	2.88	2.7	3.24
Quality	3.33	2.7	2.7	2.7	2.7
Clients loyalty	2.58	1.71	1.88	2.25	2.25
Human Resources	3.4	2.55	3.06	2.55	3.06
Scientific Knowledge	3.4	1.7	2.55	2.55	3.06
R&D	2.7	2.5	2.03	2.25	2.25
Overall rating	17.75	14.04	15.09	15	16.56

According to the information collected during the interviews, a classification of GenoMed and its most important rivals in the molecular diagnostics market was performed on the key success factors for the firms of this industry, being possible to conclude that all the firms closely compete in this market. However, the most prominent firm in the overall context of the industry is GenoMed, mostly due to strong client loyalty, human resources, research and development, scientific knowledge and quality. The weakest performance in the KSF by GenoMed is its price, where rivals reach better competitive positions.

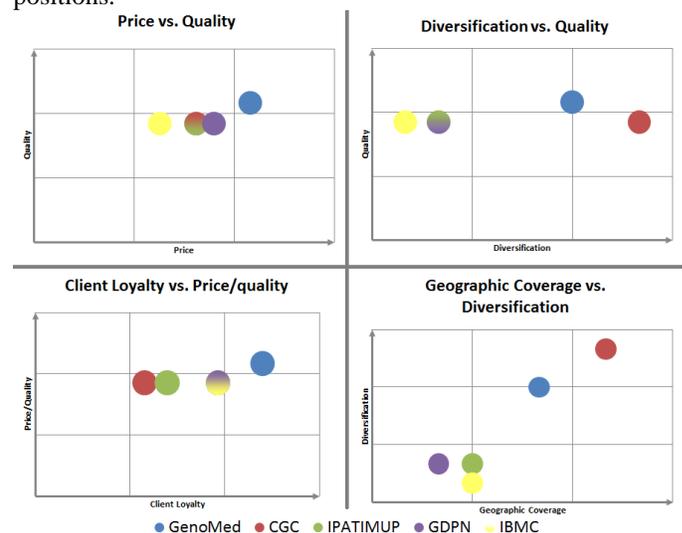


Figure 4 - Strategic group mapping of the most important firms of the market.

From strategic group mapping analysis represented in Fig. 4, it was possible to conclude that GenoMed's prices are higher but a higher quality is offered, when compared to its rivals, being this higher price/quality ratio one of the reasons behind higher clients' loyalty. Also, the great diversification of tests offered within the company didn't compromise its quality, contrasting to CGC in this point. By comparing the geographic coverage of the firms against the diversification of the portfolio of tests offered, it was possible to conclude that the best established firms on the market, GenoMed and CGC, have higher punctuations in both factors, which means a wider market and broader portfolio of tests is important in market's penetration.

V. DISCUSSION: INTERNATIONAL STRATEGY DEFINITION

From the previous analysis, a strategic plan was crafted for GenoMed's internationalization. The different phases and approach important to strive in this industry are described in this plan.

A. Pre-Internationalization Phase

Currently, GenoMed has a strong diagnostics presence, with a broad portfolio of tests to offer, however clearly lacking commercialization capabilities to push the company a step further into growth expansion.

In order to increase opportunities and to prepare to fully explore foreign opportunities, actions towards awareness creation around GenoMed's operations need to be accomplished, both in academic and industry environments, and with improvement not only in traditional sales and marketing, with marketing campaigns for services promotion, but also medical affairs capabilities with physicians.

The development of partnerships with pharmaceutical companies for biomarkers and companion molecular diagnostic tests will allow the development of new tests through shared investment in R&D. However, these relationships might be beneficial not only in the scientific and technical field, as the collaborative development of these products might lead to co-marketing and sales by both companies, providing cheaper advertising and deep learning on commercial and marketing knowledge.

One of the weaknesses GenoMed presents is its commercial and marketing skills, which could be surpassed through direct recruitment of one commercial manager with prior knowledge in these areas. Also, continuous expansion and maintenance of the existing network of contacts should be performed.

B. Generic Competitive Strategy

The best generic competitive strategy for Genomed is a Focused Differentiation Strategy, since this differentiation strategy best suits the wide variety of medical specialties and tests portfolio existing in this medical field, and the focused strategy is adapted to the highly specialized molecular diagnostics niche, since big clinical analysis groups don't assume it as crucial to their success due to difficult specialization and technical know-how.

For this strategy to work, GenoMed is required to commit to best serve clients' necessities than rivals, never distorting the firm's strong brand and recognized quality.

For GenoMed, one good win bet would be to continue the investment in rare diseases and personalized diagnostics,

where the company's image is already strong, and where tests standardization will lately take place.

C. Internationally Competing Approach

From the analysis of the clients' decision criteria and the information collected during interviews, it is possible to assume that client needs in different countries are very homogeneous. Also, strategic standardization across different areas becomes truly beneficial for efficiency and quality control purposes, one of GenoMed's competitive advantages, beside the fact that transportation of biological material (blood samples) does not imply high costs. It is therefore possible to conclude that the strategic approach that best suits these characteristics is the **global strategy**.

Through this strategic approach, GenoMed will try to achieve scale economies in diagnostic tests, powered by the NGS techniques standardization, so it might not only lower the prices of its services, one of the weaknesses identified in the competitive analysis, but also increase its bargain power against suppliers (by buying in bigger quantities) and broadening the clients portfolio of the firm, currently highly dependent on Centro Hospitalar Lisboa Norte (CHLN).

Global strategies have relatively centralized value chain activities, allowing for great efficiency, economies of scale and added expertise. Also, by spreading the risks and fixed costs over a higher output volume, it allows for higher resources commitment in R&D. However, although the general global approach, a certain degree of adaptation is needed in order to adjust the international strategy of the firm to the different needs of distinct international settings. This strategy of difference is also called arbitrage (Ghemawat 2003), residing the variances in geographical locations, developing index and economic characteristics of the target countries.

D. Strategic Option for Entering International Markets

According to the most important factors on the internationalization decision making process, different entry modes might be chosen to better fit the necessities of each market. Therefore, depending on the available resources, the control necessity of the firm, the transaction costs/barriers and the network of contacts the company have, the best market entry strategy was crafted for three different sets of countries: Eastern-Europe countries, countries with fast growing economies and rest of the world.

1) Eastern-Europe Countries

In countries from Eastern Europe like, for example, Hungary and Czech-Republic, the main target of GenoMed would be to form alliances with local firms for samples collection and posterior sending to GenoMed's laboratory for molecular diagnostic tests to be performed.

In these countries, increasingly developed laboratories and health facilities, increasing access from population to healthcare and lack of technological support, as well as scientific knowledge and technical expertise, would provide the firm a window of opportunity to establish important partnerships and alliances with local laboratories.

This entry mode would allow entering foreign markets without financial investment, requirement impossible to fulfill due to the financial status of the firm, as well as to avoid regulatory

and ethical hurdles by relying that responsibility on local partners. As disadvantages, different language and cultural barriers might cause communication problems and slow trust building, prejudicing the partnership success.

2) *Countries with Fast Growing Economies*

For countries with fast growing economies like Brazil, China, United Arab Emirates (UAE) and India, for example, excellent health facilities and highly developed laboratories are being assembled for private-pay clients, with access to top of the range technology and products. The differentiating factors for GenoMed to take advantage in these regions would be the lack of scientific knowledge and technical know-how, by taking advantage of its highly qualified collaborators, strong scientific knowledge and technical expertise in performing molecular diagnostics. The establishment of licensing relationships or cross-shareholding contracts, where GenoMed would provide its competencies in exchange of royalties or partial ownership, would allow taking full advantage of core competencies and increasing its revenues without investment requirements. However, licensing of non-patented processes might be difficult to control, especially in countries with low regulatory control, being necessary to cover that risk when crafting the contract.

In order to attract foreign businesses to form partnerships of different kinds where GenoMed would be responsible to provide scientific knowledge and technical proficiency, high investment in awareness creation in industry and medical conferences would be essential. There, the strong brand and certified and recognized quality of the laboratory would have to be publicized, together with the deep connection GenoMed has with IMM, a highly recognized international scientific institution, and FMUL and HSM physicians.

3) *Rest of the World*

For the rest of world, the strategic approach to different markets would pass by continue the existing strategy of sporadic tests requirement, either by punctual partnerships or through international rare diseases portals like Orphanet.

Markets from recently emerging economies like Angola and Mozambique should be taken into account, as future possible internationalization markets, since no demand for this kind of services exists yet. A few years from now, when health facilities, healthcare quality and the index of development of this countries rises, the cultural connection and language similarity could mean great benefit for first mover advantage when entering these countries markets. Therefore, strengthening of the existing network of contacts and new connections would be recommended, in order to smooth the market penetration when the right timing comes.

VI. CONCLUSIONS

For GenoMed, and most of similar Portuguese medicine small firms, internationalization is a present-day concern, reinforced by the decrease of internal demand caused by economic crisis, which is forcing these firms to expand its operations abroad in order to surpass the high dependence of specific clients.

From the molecular diagnostic industry analysis, it is possible to conclude that an evolution is occurring at fast pace, which will culminate with the introduction of NGS techniques in the

day-by-day practice of this field, completely revolutionizing molecular research, its clinical applications and the medicine in general in a five years period. With the introduction of these technologies, standardization will be a reality and will allow the entrance of big clinical analysis groups, contrasting to the highly specialized niche we found today, therefore increasing an already highly competitive market. Also, regulatory and legal frames should be created, so firms have the needed stability to develop their processes. Political measures regarding economic investments for co-payments of these tests should also be taken, so clinical validity and economic-value of molecular diagnostic tests can be proved and its utilization becomes regular.

Regarding GenoMed's current strategy, from the internal analysis conducted in this work, it is possible to assume it is not tailored to success, since no work is being done in order to fully leverage the most important resources and capabilities of the firm. This misfit strategy, mainly directed to one single client, caused last year financial state of GenoMed to worsen, since the economic crisis obliged this client to lower the demand for new diagnostic tests. Also, since most of the divulgation has scientific purposes, no commercial benefits are being extracted from it.

From resources and capabilities analysis and most important factors for markets success study, it was possible to understand that GenoMed's most important advantages are its strong scientific knowledge and technical know-how, backed up by top-edge technology access and highly qualified human resources. Also, its integration on a health cluster like IMM and its proximity and relationship with medical corps should ground a successful strategy for internal and international markets.

Using the acquired knowledge from the industry and internal analysis, combined with the information collected during literature review, a strategic approach for GenoMed's internationalization was created. It should maintain its market niche approach, but should also consider the internationalization of its activities. This strategy starts with a solid preparation prior to international operations, by creating managerial engagement to this objective and strategic awareness in industry related congresses and medical environments. At the same time, a strong investment in expanding and fortifying the company's network of contacts should be made, forming strategic partnerships with bi-pharmaceutical firms and important scientific research institutes in geographic areas of interest, in order to strengthen the perceived credibility and trustworthiness of GenoMed in these areas. Knowledge acquisition in international marketing and commercial fields are also encouraged, mainly by hiring an experienced manager to lead these operations.

The strategy for the internationalization process of GenoMed should follow a global approach, with standardization of practices around the globe, with alliances formation in geographic areas of interest. The three main clusters of countries were formed:

1. Eastern-Europe countries, with strategic alliances formation for tests outsourcing to GenoMed, making use of their network of contacts in this region;

2. Countries with fast growing economies, like China, Brazil and UAE, where partnerships based in cross-shareholding and licensing could be made, providing GenoMed the scientific knowledge and technical know-how in exchange of royalties or participation in these firms;

3. Countries from the rest of the world, where no specific strategic moves are advised, unless the credibility and trustworthiness consolidation and network relationships development, especially in countries like Angola or Mozambique where, in the future, a preferential position will constitute an important competitive advantage.

In conclusion, although this internationalization strategy has been developed for GenoMed, since market conditions and industry environments are similar for any other small Portuguese academic start-up firm operating in the market niche of molecular diagnostic market, this internationalization strategy can be generalized and advised for them.

REFERENCES

1. AdvaMedDx, 2013. *The Essentials of Diagnostic Series: Introduction to Molecular Diagnostics*,
2. Ansorge, W.J., 2009. Next-generation DNA sequencing techniques. *New biotechnology*, 25(4), pp.195–203.
3. Bell, J., 2003. Towards an Integrative Model of Small Firm Internationalisation. *Journal of International Entrepreneurship*, 1, pp.339–362.
4. Brennan, L. & Garvey, D., 2009. The role of knowledge in internationalization. *Research in International Business and Finance*, 23(2), pp.120–133.
5. Ghemawat, P., 2003. The forgotten strategy. *Harvard business review*, 81(11), pp.76–84, 139.
6. Goverman, I.L., Jacoby, R. & Lester, R.G., 2012. *Bench to bedside: Formulating winning strategies in molecular diagnostics*,
7. Griffiths, A.J.F. et al., 2012. *Introduction to Genetic Analysis* 10th ed., W. H. Freeman and Company.
8. Johanson, J. & Vahlne, J.-E., 1977. The internationalization process of the firm - a model of knowledge development and increasing market foreign market commitments. *Journal of International Business Studies*, 8(1), pp.25–34.
9. Klug, W.S. et al., 2012. *Concepts of Genetics* 10th ed., Pearson.
10. Kotler, P., 1994. *Marketing Administration: Analysis, Planning, Implementation and Control* 3rd ed., São Paulo: Atlas.
11. Mcgee, J. & Bonnici, T.A.S., 2002. Network industries in the new economy. , pp.116–133.
12. Morozova, O. & Marra, M. a, 2008. Applications of next-generation sequencing technologies in functional genomics. *Genomics*, 92(5), pp.255–64.
13. Oviatt, B.M. & McDougall, P.P., 1994. Towards a theory of international new ventures. *Journal of International Business Studies*, 25(1), pp.45–64.
14. Oxford Dictionaries, 2010. Internationalize. *Oxford University Press*. Available at: <http://oxforddictionaries.com/definition/english/internationalize?q=internationalization> [Accessed December 6, 2012].
15. Prweb, 2013. *Molecular Diagnostics Market & Forecast to 2017: Global Analysis*, London.
16. Raskin, A. & Casdin, E., 2011. *The Dawn of Molecular Medicine*,
17. Rasmussen, E.S. & Madsen, T.K., 2002. The Born Global concept: Paper for the EIBA conference. In *28th EIBA conference*.
18. Strachan, T. & Read, A., 2010. *Human Molecular Genetics* 4th ed., Garland Science.
19. Styles, C. & Genua, T., 2008. The rapid internationalization of high technology firms created through the commercialization of academic research. *Journal of World Business*, 43(2), pp.146–157.
20. Tan, A., Brewer, P. & Liesch, P.W., 2007. Before the first export decision: Internationalisation readiness in the pre-export phase. *International Business Review*, 16(3), pp.294–309.
21. Thompson, A.A. et al., 2012. *Crafting & Executing Strategy: Concepts and Cases: Global Edition* 18th ed., McGraw-Hill-Irwin.
22. UNIDO, 2006. *Alliances and joint ventures: Patterns of internationalization for developing country enterprises*, Austria.
23. World Medical Association, 2009. WMA Statement on Genetics and Medicine. , (October 2005), pp.1–5.
24. Xuan, J. et al., 2013. Next-generation sequencing in the clinic: promises and challenges. *Cancer letters*, 340(2), pp.284–95.
25. Yin, R.K., 2009. *Case Study Research: Design and Methods* 4th ed., SAGE Inc.