

TRANSATLANTIC COMPANIES – WORTH THE HASSLE?

At the turn of the 20th century, European universities were undoubtedly the dominating research institutions in the world. Einstein, Heisenberg, Bohr, Schroedinger and Pauli, among many others, changed forever our understanding of matter. Chemists who today are largely forgotten developed the first drugs, including aspirin and even LSD. Felix Hoffman probably synthesized aspirin when working at Bayer, but the story is not that simple (<http://www.mjm.mcgill.ca/issues/v02n02/aspirin.html>). Another Hofmann, Albert discovered LSD in the Sandoz chemical-pharmaceutical laboratories in Switzerland (<http://www.druglibrary.org/schaffer/lsd/grofhist.htm#sec1>). The first drugs ever released were supposedly Sulphonal, a sleeping medication, and Phenacetin, a close cousin of Tylenol. Bayer began to sell these compounds in 1888. Companies such as Bayer, Hoechst and Ciba-Geigy were able aggressively to expand their lines of business from dye discovery and manufacturing to become global pharmaceutical giants. Other companies that rode this wave of expansion and development still survive, although sometimes under different names.

At the dawn of the 21st century, the landscape has changed. American universities are now dominant. Due to the excellent research environment in the US during the last decades, a new generation of pharmaceutical companies, now called “biotechnology companies” has been able to arise, mainly on the West Coast and East Coast of the US. Most of these companies have been nurtured by technologies and talent transferred from a few universities.

European initiatives to close the gap between the US and Europe in this regard commenced in earnest at the beginning of the last decade and have resulted in the incorporation of more than 300 biotechnology companies in Germany alone. Qiagen (NASDAQ: QGENF) is certainly one of the winners, one of the few as yet.

A significant enabling factor in this biotechnology boom has been the availability of venture capital, money from investors at an early stage in the life of a company. “The composer of the term ‘venture capital’ is unknown, and there is no standard definition of it. It is, however, generally agreed that the traditional venture capital era began in earnest in 1946, when General Georges Doriot, Ralph Flanders, Karl Compton, Merrill Griswold and others organized American Research & Development (AR&D). It was the first (and, after it went public, for many years the only) public corporation specializing in investing in illiquid securities of early stage issuers.” This citation and more information are published under <http://www.vcexperts.com/Library/Articles/c1a2.htm>. Through his teaching at the Harvard Business School, Doriot was instrumental in the development of the venture capital community in the US. However, although Doriot was French, Europeans generally were risk-averse and

uncomfortable with his investment philosophy. Even the 1957 founding of INSEAD by Doriot, a European business school respected throughout the world, could not break the resistance. Instead, it took several decades before Doriot's vision developed sufficient maturity and venture capital became available in Europe.

Since the beginning of the biotechnology movement in Europe at the end of the 1980s, biotechnology companies have had to wrestle with the following key questions:

Can Europe provide enough scientific and management talent?

What is the best way to get access to the most lucrative health care market in the world?

Are the European financial markets ready to invest in young, high-risk companies?

Are Governments willing to subsidize the first steps? In the US, SBIR, STTR, DARPA, ATP and other grants help during the early stages.

Are Governments willing to change the strict requirements concerning animal experiments, genetic manipulations, and the like that clearly have hindered scientific progress in Europe since the late 1980s? One reason for the slow start of the biotechnology movement in Europe has been the very cumbersome regulatory environment. Some European pharmaceutical giants moved their research divisions to the US or simply acquired US based biotechnology companies. In the middle of the 1990s the German government eased the regulatory environment and today it is not a significant disadvantage.

Will the anti-biotechnology mentality (present in the mid 1980s until the early 1990s) allow the development of biotechnology companies? Hoechst had difficulties building a manufacturing plant for the production of recombinant proteins using bacteria. This negative attitude disappeared in the mid 1990s, strongly influenced by significant biotechnology investments in the Bavaria/Munich region.

Will the anti-Genetically Modified Organism mentality negatively influence the growth and maturation of biotechnology companies?

Perhaps partially driven by the struggle to find answers to these questions, partially by already established networks, partially by serendipity, transatlantic companies were built, companies that had European and US roots from the beginning. Examples that fit our definition are Sequenom (NASDAQ: [SQNM](#)), GPC (FRA: [GPCG](#)) and Coley Pharmaceuticals (private) among others. It is still too early to evaluate decisively whether this transatlantic model will prove more successful than simply beginning a company in one region and then migrating to other regions later.

The remainder of this article will discuss some of the issues that transatlantic companies have faced.

CULTURE CLASH

Although different European countries try to portray themselves as unique in their cultural values, the blending of European and American culture is clearly evident, for good or bad. Not everyone accepts or welcomes this trend, as one could see during different “world” meetings in Seattle, Prague and Genoa. In a recent poll in France, 12% said that they admired the United States, 46% were critical or worried and 75% wanted less American influence on “economic and financial globalization” (The Economist, August 4th, 2001). The integration of the European and American ways of life presents many hurdles including the following:

Language: Certainly important and to be incorporated in the hiring philosophy; a person’s lack of adequate language abilities can block efficient communication. This problem is decreasing in importance, as English is now a mandatory language in most European schools, and factors such as computer and Internet use have helped to make younger generations more fluent in English than their elders.

Time Zone: Efficient communication can be difficult with offices spanning different time zones.

Attitude toward Risk: Europeans tend to be more risk-averse than Americans. However, this attitude is changing, partly as a result of the success of the American stock markets and partly as a result of the emergence of successful European entrepreneur role models.

Employee Contracts and Benefits: Europeans typically receive 5 or 6 weeks of vacation and a comprehensive health insurance package. The habit of working long hours is less common in Europe than the US. Thirty five or 38 hour weeks are mandated in some countries and are under serious consideration in others.

Unions: The backlash against unions evident in some sectors of US business has not yet spread to Europe to any significant extent.

Options and Ownership: Until recently, Europeans showed a strong preference for cash compensation. Stock options were rarely offered or sought.

Hierarchy: Americans still “enjoy” a more flat organizational structure and attitude; titles are less frequently used and the dress code can be quite flexible.

Educational System: American and European educational systems show significant differences: “elite” versus public, “infiltrated by capitalism” versus “pure”, applied versus theoretical, privately versus publicly financed. This topic certainly deserves an extra article.

Cultural Values: working hours, length of commute, mobility, job security, “loss of cultural identity anxiety” (French farmer destroys McDonald restaurant), loyalty to employer,

life-long job prospect, etc.

One advantage of a transatlantic company is an increased network of contacts. Two individuals from the Boston area working for several years in biotechnology will probably have an overlapping network. A German individual and an American individual working in the biotechnology space should have a broader network because less overlap should exist. It is not clear, however, whether the depth of a corporate network increases the probability of success. One bullet point above contrasts the educational system in the US and Germany or Europe. I have experienced both systems and although the differences are significant, both worlds have unique advantages and disadvantages. It is probably a significant competitive advantage for a company to be able to draw from a pool of employees with experience from both sides. Diversity is a clear advantage if unavoidable tensions due to the cultural diversity can be efficiently managed.

MANAGEMENT ISSUES

Management must deal with these cultural differences and the resulting problems. Individuals with experience in both worlds are certainly better equipped to deal with these issues than candidates with purely local experience. Because the biotechnology industry is still relatively new in Europe, there is a shortage of experienced European managers. Merger activity involving the pharmaceutical industry may free up more managerial talent. But the mindset required managing a young biotechnology company is significantly different from that fostered within a pharmaceutical giant. According to one of our partners, executives who make the transition from “big pharma” to a small biotechnology company can feel a strong boost and find themselves rejuvenated by the new working environment.

In addition to the talent released by the mergers, a new generation of young biotechnology managers must be trained. In the US in the early 1970s when the new generation of biotechnology companies started to develop, the educational system helped to fill this gap. First, the US has more excellent business schools per student and therefore the probability of a double education (biology or biochemistry followed by an MBA) is higher. Second, undergraduate programs in the US tolerate combinations like economics and biology. In Europe these career paths are very often not possible. Third, Americans “just did not care” whether somebody had experience or not. Bill Gates and friends did not have much experience in running a business. In Europe the attitude is more conservative. Only in the last few years has the “MBA mentality” gained popularity in Europe. Because of the complexity of the science behind biotechnology, dual degrees are very valuable, if not essential, but individuals with both

competencies are rare. More focus on combined programs might slowly fill the gap.

Although many still consider the US to have a cheap labor pool compared to Europe, I doubt that this is true for high-technology companies. The enormous compensation packages granted during the Dot.com bubble support this hypothesis. Today, my guess is that it is cheaper to run a biotechnology company in Germany than in the US. However, I could not find adequate numbers to substantiate this claim. Income inequality is much more pronounced in the US than in Europe, but if you need to hire supporting staff you are probably better off in the US. A generous stock option package expected by new employees constitutes a substantial extra cost, although Europe is catching up on this habit quite rapidly.

Although integrating two or more cultures may be difficult, the resulting diversity may provide a significant advantage. Management studies have shown that the problem solving ability of groups increases with the diversity of the people involved (see for example: Putting your company's brain to work by Dorothy Leonard and Susaan Straus, HBR July-August 1997). On the other hand, frustration resulting from different worldviews can grow, and it is therefore important to be alert for potential transatlantic conflicts. It is difficult enough to solve cultural tensions at one working location; the problem is exacerbated when multiple locations several thousand miles apart are involved. Nevertheless, the potential of improved problem solving ability resulting from increased diversity is one area where the transatlantic company has significant advantages over single country organizations. At this moment it is too early to analyze adequately whether this advantage can be expressed in monetary terms.

FINANCIAL CONSIDERATIONS

One reason for the biotechnology boom in Germany was the significant support of the German Government and local authorities. This support took the form of subsidies without taking equity but providing downside protection up to a certain maximum. This activity has created incentives to start new entities. In addition, tax reforms were initiated across Europe adjusting the individual and corporate rates to US levels. The London Stock Exchange opened its doors to biotechnology companies in the early 1990s by lowering its listing criteria. With the opening of the Neuer Markt in Germany in the mid to late 1990s and similar exchanges in France and Switzerland, other exit vehicles became available to the venture capitalist. Transatlantic companies can elect to list their shares on different stock exchanges depending on the market conditions. It is not clear at the moment whether a dual listing is advantageous in the long run. A NASDAQ listing is still the first choice, in no small part because of daily trading volumes. For a venture capital fund, the higher the trading volume, the easier it will be to gain liquidity after the expiration of the post IPO lock-up period and thereby provide adequate returns to its

investors in a timely fashion. Is it possible for some of the new exchanges to challenge the NASDAQ as the premier high-technology bourse? Only time will tell, but European markets have gained popularity recently. In addition, a consolidation of the 30 or so stock exchanges in Europe to less than 5 in the next years is likely and will increase the attractiveness of the remaining exchanges. This could result in significant competition to NASDAQ.

Other major reasons for the popularity of NASDAQ over European exchanges include the sophistication and the experience of its investors and the more extensive coverage of its listed companies by institutional analysts. The public investors obviously also value liquidity!

For debt financing of established public companies the European financial markets, especially the London market, are comparable in sophistication to the US market. Although tax differences exist, they should not influence the decision-making process to start a transatlantic company. A clear disadvantage of running a transatlantic company lies in decentralization. It certainly increases the overhead if one has to handle different accounting and tax systems. This also applies for companies with dual listings. It is just more paperwork somebody has to do.

In the last decade European individuals started to invest more of their savings in mutual fund type investments, and the institutions began to invest in alternative assets like venture capital. If this trend continues, venture capital money should become and remain available as fund managers allocate a small percentage of their resources into high-risk ventures. This should sustain the momentum the venture capital industry has developed in the last decade.

REGULATORY ISSUES

The formation and facilitation of transatlantic biotechnology companies has been eased in recent years with regulatory harmonization efforts being undertaken by the International Conference on Harmonization (ICH, <http://www.ifpma.org/ich1.html>). The ICH process will apply to the marketing of drugs, biologics, medical devices and diagnostics. The U.S. Food and Drug Administration (FDA) and the European Agency for the Evaluation of Medicinal Products (EMA), along with Japan and Canada, have negotiated consensus guidelines (Directives). While a common global regulatory framework has emerged, there are still interpreted nuances each national regulatory group has made to assert their own prerogative. These regulatory harmonization efforts have facilitated the ability of companies to perform simultaneous clinical studies in Europe and the U.S. This allows companies to seek simultaneous regulatory approvals in Europe and the U.S. Thus companies can perform one set of pre-clinical and clinical studies to be submitted in the U.S. and Europe to support registration. Other countries have also adopted the harmonization directives making them globally accepted. Despite harmonization there are still differences, sometimes quite subtle, in terms of regulatory

approval requirements, not only between the U.S. and Europe, but also between the European countries within the European Union especially in the intended use and practice of medicine.

Companies increasingly are taking advantage of the political pressures on governmental regulatory agencies. Many international pharmaceutical and biotechnology companies have aggressively pursued approvals in the U.S., given the pressure on FDA to expedite review of marketing applications. As this pendulum has moved to an increasingly cautious FDA approval process, companies are now seeking earlier market entry into Europe, which has announced its new policy to speed the review process.

CORPORATE LAW CONSIDERATIONS

The term “transatlantic company” can be used to describe a variety of different entities: for example, an early stage US company funded by European investment, an early stage European company funded by US investment, an established European company with manufacturing, sales and marketing or other operations in the US, or an established US company with manufacturing, sales and marketing or other operations in Europe. This discussion will focus, however, on a particular type of transatlantic company: one based on European technology but organized in the US.

Why would one organize a company based on European technology in the US? Why would a young European company migrate to the US? Why would a group of European entrepreneurs want to establish their company in the US? The fundamental reason is the US product market, but underlying this fundamental factor are ancillary considerations.

Generally speaking, for most IT, biotechnology and other high tech companies, the US is the largest product market - not the only market, not the only important market, but generally the single most important market. This means that if the company is successful, it will likely have a significant presence in the US.

Assuming this significant US presence, a number of benefits arise from either organizing the business in the US initially, or migrating the business to the US at an early stage. These include the following:

- Enhanced access to the US venture capital market, the world’s largest.
- Enhanced access to the US IPO market, also the world's largest.
- Attractiveness to potential US employees, who would be able to get US style compensation packages, including stock options.
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Attractiveness to potential US customers, who would be able to deal with a "local" company.

- Attractiveness to potential US strategic partners and acquisition targets, arising from ability to issue them equity in a US corporation.

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Attractiveness to potential US acquirors in a trade sale, who will be more familiar and comfortable with the US form of entity.

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Tax considerations, including:

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Potentially unfavorable tax treatment that might arise under local European law from migration of the company from Europe to the US at a later date (for example, because of tax on the disposition of equity in a European entity in exchange for equity in a US entity after significant appreciation in the value of the European entity).

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Potentially favorable tax treatment under US tax law for certain merger-type transactions that might not be available for transactions involving European entities (for example, because of structuring impediments imposed by European corporate law).

In a typical scenario, the steps involved in organizing a transatlantic company in the US based on European technology are as follows:

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A new corporation ("Holding Inc.") is organized in the US, generally under Delaware law. This can be done very quickly. Upon being organized, Holding Inc. issues common stock to the founders in exchange for cash and/or intellectual property, or, if a European company is already established, in exchange for their equity in the existing European company.

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Next, venture capital investors purchase convertible preferred stock of Holding Inc. Depending of the structure of the particular transaction, it might be necessary to wait a period of time before this investment is made.

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A European subsidiary ("EuroCo") is formed after the venture capital investment (potentially beforehand if funds are sufficient), to handle European operations, including European research and development and European sales and

marketing. (If the first step above involved an equity exchange, the European subsidiary will already exist.)

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After the venture capital investment, much of the capital raised is invested in EuroCo (most likely in the form of equity). In some cases, this capital invested in EuroCo will qualify for European government matching funds.

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A US operating company (“USCo”) is formed as a subsidiary of Holding Inc. at an appropriate time (for example, when marketing and sales begin in the US).

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European founders (to the extent that they are intended to be employees) become employees of EuroCo; US founders (to the extent that they are intended to be employees) become employees of Holding Inc. or USCo.

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All employee stock options (including stock options for employees of EuroCo and USCo) are issued by Holding Inc. and exercisable for common stock of Holding Inc.

PATENT ISSUES RELEVANT TO TRANSATLANTIC COMPANIES

Like any company, a transatlantic company must determine at the outset the country or countries in which it or a competitor is likely to commercialize an invention and pursue appropriate patent protection. The Paris Convention, which has been signed by virtually every industrialized country, provides that patent applications filed in other member countries or an international (or Patent Cooperation Treaty (PCT)) patent application may claim priority back to a patent application filed in a first member country, so long as later applications are filed within one year after the filing date of the first patent application. This means that patent applications filed in other countries within a year of being filed in the first country will be treated as if filed in the first country for purposes of determining patentability, so that any publication, public use, or sale of the invention occurring after the first filing is not considered prior art to these later filed patent applications. In addition to delaying costs, by waiting until close to the one year anniversary of the first filing, these later filings can be more complete and can incorporate changes or developments to the invention that have occurred during the year.

Transatlantic companies in particular, which are likely to have multiple individuals working in different countries, should be aware that some, but not all countries require that inventors file

the first patent application in the patent office of the country in which they are a citizen. One reason for this requirement in the U.S. is for patent applications, which contain a disclosure that might be detrimental to the national security, may be identified and be subjected to a Secrecy Order, which would prevent filing of a corresponding foreign patent application. In spite of the requirements of the Paris Convention, this may require that multiple applications be filed at the outset. For example, patent applications should initially be filed in both the U.S. and Great Britain, if one of the inventors is a citizen of the U.S. and another is a citizen of Great Britain. Transatlantic companies should also be aware that although most countries, including all European countries, require absolute novelty for patenting inventions, the U.S. and Canada provide a one year and Japan and Australia a six month grace period in which a patent application may nonetheless be filed after the occurrence of a prior art event. In the unfortunate event that an invention is publicly disclosed, used or sold and is therefore not entitled to European patent protection, it may nonetheless be patented in the U.S., Canada, Japan and/or Australia. A European patent attorney may not always advise of this possibility. Transatlantic companies should further recognize that the U.S. has the strictest requirements for adequately describing and enabling an invention in the patent application. As a result, regardless of where a patent application is to be initially filed, it is usually advisable to have a U.S. patent attorney draft the patent application to satisfy the more stringent U.S. requirements.

Conclusion

Starting and developing transatlantic companies is a complex undertaking and to increase the likelihood of success an experienced team of different professionals needs to work together. TVM has proven in recent years that it has access to such a team and will use its professional network also in the future to form successful transatlantic companies.

Thomas Boehm from TVM is responsible for the content; nevertheless many individuals at TVM contributed to this article; Bruce Mackler from Heller, Ehrman, White & McAuliffe LLP wrote the section about Regulatory Issues; David Pierson added the section about the Corporate Law implications, improved significantly the style and Beth Arnold contributed the paragraphs about Patent Issues. Both work for Foley Hoag & Eliot LLP in Boston. For questions and comments please contact boehm@tvmvc.com.