

The Emergence of the Bio-Nanotechnology Industry

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Abstract

We examine the emergence of the bio-nanotechnology industry by identifying, classifying and tracking the entry and exit of firms of various sizes, regions and application focus over time and by observing the degree to which they integrate nanotechnology with biotechnology.

Keywords: Nanotechnology Commercialization; Biotechnology Commercialization; Confluence of Technologies; Industry Evolution; Knowledge Integration; Drug Delivery; Diagnostics; Bio-Nanotechnology; Nano-Biotechnology

The Emergence of the Bio-Nanotechnology Industry

Nanotechnology has enjoyed a tremendous boom in research over the past 15 years, but commercialization has lagged^{1,2}. One of the most exciting and promising sectors of nanotechnology is that applied to biological processes^{3,4,5}. Part of the reason for this huge potential is the integration of two previously disparate fields of research. Novel combinations of ideas and elements, such as those which occur when two previously separate technological disciplines interact, are a known way to increase innovative opportunity⁶.

The rate of increase in bio-nanotechnology invention is well documented^{7,8}. However, little is known about the commercialization of these inventions and the entry of firms into this field. What types of companies have both biotechnology and nanotechnology capabilities, when and where did they develop them, and what applications are they targeting? Are they actually integrating nanotechnology with biotechnology? Here, we examine the emergence of the global bio-nanotechnology industry by identifying, tracking, and analysing all of the firms globally with capabilities in biotechnology and nanotechnology, and observing the degree to which they integrate their knowledge.

Entry and Exits of Bio-Nanotechnology Firms by Firm Type

Through extensive search and validation, we identified 507 firms globally which have capabilities in both biotechnology and nanotechnology. We categorized these firms by firm type and by industry sub-sector. We then tracked the entry and exit of these firms, including mergers and acquisitions.

Our analysis shows that bio-nanotechnology capabilities first emerged in multinational corporations in the late eighties and early nineties (Fig. 1). Most of these multinational corporations are based in the chemical (e.g. Dow, Bayer), pharmaceutical (e.g. Roche, Abbott Labs) or the electronics (e.g. HP, Hitachi) industries. Most have developed capabilities in biotechnology and nanotechnology in separate subsidiaries and have supplemented their capabilities by acquiring smaller bio-nanotechnology firms. It may be surprising to note that there were already 10 multinational corporations with both biotechnology and nanotechnology capabilities as of 1990 (Fig. 1): in fact, such areas of nanoscale research as liposomes and micelles (now considered within the realm of nanotechnology) existed in biotechnology and polymer chemistry research as early as the 1960s. Bio-nanotechnology applications began to emerge in the early 1990s, after the development of the scanning tunneling microscope and the atomic force microscope¹.

< insert Figure 1 here >

As of 1999, the majority of the firms in the emerging bio-nanotechnology sector were *de novo* firms, which we define as new firms founded specifically to commercialize the opportunities arising from the confluence of biotechnology and nanotechnology. De novo firms rapidly increase in number between 1995 and 2007 (Fig. 1), with a total of 215 de novo firm entries during that time period. The timing of these entries is consistent with the assertion that start-up firms are more likely than large, established firms to attempt to commercialize highly uncertain R&D^{3,9,10}. In the emerging bio-nanotechnology industry, approximately two thirds of the firms with bio-nanotechnology capabilities are very small as measured by annual revenues^{3,11}. Thus, ventures can be considered the primary driver for innovation in such highly

diverse fields. One prominent bio-nanotechnology inventor and entrepreneur stated that he needed to form start-ups because when he licensed his diverse technologies to large firms they often did not develop these technologies further¹². A de novo exemplar is depicted in Box 1. Our data also showed a steep decline in the number of de novo entrants during and post 2008. It is likely that this decline reflects financing constraints during that period¹³.

<insert Box 1 here>

We define *de alio* as incumbent firms which have chosen to enter the bio-nanotechnology industry. De alio firms are differentiated from multinational corporations because they are smaller in size, have fewer (or no) subsidiaries, and have much less geographic scope. De alio firms are often established biotechnology firms which enter the bio-nanotechnology industry through development of their own capabilities in nanotechnology or by acquiring existing firms which have demonstrated success in integrating biotechnology and nanotechnology. We find that the de alio firms started entering this industry in significant numbers post 1998 with a peak in the year 2005. After a period of lesser entry post-2008, further entry by de alio firms is noted in 2011 (Fig. 1).

Although multinational corporations have significant nanotechnology capabilities, we find that their main focus remains on their existing industries and technologies: only a very small proportion of their total patents can be classified as bio-nanotechnology patents (on average 0.1%, versus an average of 9.9% for de novo firms and 3.0% for de alio firms). This highlights the tensions between existing capabilities and emerging capabilities within large, established organizations as described by Maine⁹, who identifies pressures suppressing radical innovation in the chemicals multinational corporation Degussa. Thus, despite first-mover advantages and

superior resources, it is the small, fledgling experiments, in the form of de novo firms tightly integrated to universities, which appear most likely to cross-pollinate concepts from different disciplines and commercialize the resulting bio-nanotechnology inventions.

Evolution of the bio-nanotechnology industry across countries and regions

Based on extant innovation literature¹⁴, we expected national and regional differences in the evolution of the global bio-nanotechnology industry. Similar to other technology based industries, the evolution of the bio-nanotechnology industry globally has not been homogeneous. As depicted in Fig. 2, we find that the USA leads the emergence of this industry, with approximately 60% of global bio-nanotechnology firms located there. Predominant regional strengths are found in California, Massachusetts, and New York & New Jersey. Somewhat surprisingly, the rest of the USA also has a substantial and growing proportion of bio-nanotechnology firms, outside of traditional biotech clusters. As an example, the highly integrative bio-nanotechnology diagnostics venture, Nanosphere (see Box 1), was spun out of Northwestern University and is building its manufacturing facilities in Northbrook, Illinois. This suggests that that star scientists in research universities are the most important determinant of the location of new bio-nanotechnology firms, as was found by Zucker et al.¹⁵ in the formation of the biotechnology industry in the 1970s and 1980s.

<insert Figure 2 here>

Germany, the United Kingdom, Japan, Canada and Australia all have a significant bio-nanotechnology presence, with 10 or more bio-nanotechnology firms. Germany has been the leading European country throughout the evolution of the bio-nanotechnology industry, but may

be challenged in that role with a proportional decrease in their share of bio-nanotechnology firms over time, from 37% of the European firms in 2005 to 24% in 2011 (Fig. 2). As in the USA, the entry of bio-nanotechnology firms outside of the traditional biotech clusters in Europe has been extensive and has continued through the financial crisis. Several countries like Sweden, Netherlands, Spain and Italy have new entrants between 2008 and 2011. France is an interesting case, with minimal bio-nanotechnology activity in 2005, but 14 firms by 2011, with a predominance of de novo drug delivery firms.

<insert Table 1 here>

The predominant bio-nanotechnology region in Austral-Asia is Japan. Australia, New Zealand, South Korea, China, Israel, and India also have a presence. The Austral-Asian region accounted for 14% of global bio-nanotechnology firms in 2011, with rapid growth in firm entry from 2005 to 2008, and slower growth since 2008, but little change in the overall global share.

The overall picture that emerges is the rapid growth of this industry globally before 2008 (51% between 2005 and 2008), slowing down substantially after 2008 (17% between 2008 and 2011). Regions have evolved in notably different ways, with the Massachusetts firms representing all subsectors of bio-nanotechnology and a roughly equal mix of de alio and de novo firms. France, on the other hand, fostered impressive growth in a focused bio-nanotechnology subsector, suggesting that purposeful science policy can play an important role in this emerging industry.

Bio-Nanotechnology Industry Evolution by Industry Sub-Sector

Bio-nanotechnology encompasses several industry sub-sectors with notable differences in application focus. Table 2 provides example of types of firms categorized in each bio-nanotechnology industry subsector. Following studies of industry evolution which track firm entry and exit over time¹⁶, Fig. 3 depicts firm entries and exits into four bio-nanotechnology industry sub-sectors: bio-pharmaceutical, drug delivery, suppliers & instrumentation, and diagnostics. Bio-pharmaceutical firms, the most prevalent subsector of the bio-nanotechnology industry, were early entrants into specific areas of bio-nanotechnology research, such as utilising liposomes for drug delivery. Both the bio-pharmaceutical and drug delivery subsectors experienced a rapid increase in firm entry from 2004-2008 (Fig. 3). Entry into the supplier & instrumentation sub-sector began earlier, with rapid firm entry around 2000, but began to plateau in 2005.

<insert Table 2 here>

Industries evolve over time in known patterns, moving from the fluid phase to the transitional phase to the specific phase with each phase having characteristic rates of product and process innovation, and associated changes in firm entry & exit, R&D management, organizational characteristics, market focus, and competitive focus¹⁶. In several studies of the evolution of industries, a dominant design - a standard set of product features or technological attributes which become expected by the marketplace – emerges after a period of rapid entry of firms and instigates consolidation of firms in the industry. Although easier to analyze in hindsight, our data suggests that one or more dominant designs may have emerged in the supplier & instrumentation sub-sectors: the rapid growth and subsequent plateau depicted in Fig. 3 may

be indicators of a shift in the phase of industry evolution. A dominant design in this industry sub-sector could be processes in the synthesis of nanoparticles. Scientists and engineers in these firms should thus be more focused on process attributes, such as reducing cost and increasing reliability, and less focused on developing new product features or technological attributes.

<insert Figure 3 here>

The diagnostic and drug delivery sub-sectors appear to be toward the end of the fluid phase of industry emergence. In this phase, there remain great opportunities for radical innovation and the focus is on competing on product features or technical attributes. That said, the rate of entry has reduced in these sub-sectors, and potential dominant designs are emerging among drug delivery technologies^{17,18}. Our data on the degree of integration of bio-nanotechnology knowledge in bio-pharmaceutical firms suggests that they may only adopt a dominant design from the drug delivery firms, rather than contribute to forming it. Bio-pharmaceutical firms are likely to focus more on the new drug and less on the delivery mechanism, choosing to adopt and, where necessary, adapt, mechanisms developed by drug delivery specialist firms.

Conclusions

The first firms to develop capabilities in both biotechnology and nanotechnology were multinational corporations. However, these capabilities often remained in silos and remain overshadowed by the multinational corporations' existing capabilities. De novo firms began to emerge around 1995 and appear to be the primary driver for innovation in such highly diverse

fields. De alio firms, largely biotechnology and pharmaceutical firms, developed capabilities in nanotechnology with a peak of entry into bio-nanotechnology in 2005. Many of these firms were utilizing nanotechnology to further improve their existing diagnostics and drug delivery capabilities.

Different regions have followed very different approaches in building bio-nanotechnology strengths. The USA dominated the early emergence of this industry and remains dominant today. Germany, although still the dominant European country, has a decreasing share of firms in the European bio-nanotechnology industry. Intriguingly, regions outside existing biotechnology clusters are spawning many firms in this emerging industry, with a strong research university appearing to be the prerequisite for de novo firm entry. This finding suggests that opportunity still exists for regions to support bio-nanotechnology emergence through science policy.

Industry subsectors are at various phases of evolution. The drug delivery and diagnostics sub-sectors appear to be coalescing around potential dominant designs, but still compete on technological attributes. As such, their focus is still on product innovation, and establishing the dominant design. In the supplier & instrumentation sub-sector, the rapid entry period appears to have concluded. This suggests that these firms should be focussing on process innovation and subsequent cost reduction.

We argue that those knowledge-based sectors drawing on a diverse range of novel inputs, such as biotechnology and nanotechnology, will be most likely to provide opportunity for radical innovation and economic growth. But integration of such disparate technological fields is not straightforward, especially for multinational corporations. Firms can increase their chances at

benefiting from emerging industries such as bio-nanotechnology by enhancing the exchange of ideas across technology fields and knowledge workers. Co-location of diverse groups, purposeful mixing of disparate expertise and insulation from an incremental innovation culture are recommended^{9,19,20}. Hiring of scientists and engineers with an interdisciplinary education could also help bridge technology silos. Such practices would accelerate the transition of the enormous promise of bio-nanotechnology confluence into economic and social value.

Governments can also influence innovation in industry by providing resources and by creating an environment encouraging innovation. Measures that have been proven most effective are government funding of research, ensuring a broad and strong system of education, and ensuring a robust and resilient infrastructure^{4,21,22}. We have observed in our data here and in other studies that new entrants in emerging industries tend to be clustered in a few locations that might be said to have a strong and balanced ecology: of research centers, talented human resources, excellent transportation, communication and other assets supporting innovation²³. The increasing entry of firms outside of traditional biotechnology clusters suggests that science policy can play a strong role in this emerging industry, with research universities as the hubs.

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Figure1: The Evolution of the Global Bio-nanotechnology Industry by Firm Type

- De Novo: Firms where the difference between the founding year and year of acquisition of nanotechnology capability was 3 years or less
- De Alio: Firms where the difference between the founding year and year of acquisition of nanotechnology capability was more than 3 years
- MNC: Multinational Corporation

Box 1: Example of a highly integrated start-up firm: NanoSphere

- Nearly entire biotechnology or nanotechnology patent portfolio integrated
 - Founder Chad Mirkin is a pioneer in the integration of nanotechnology with biotechnology
 - 46 out of 50 US patents incorporate both biotechnology and nanotechnology
 - “We live at the boundaries of molecular diagnostics and nanotechnology” Bill Moffit, former CEO Nanosphere.
- De Novo Bio-Nanotechnology Diagnostics Firm
 - Earlier detection of disease and more targeted treatment
 - World’s first diagnostic test for sepsis, shortening time from 3 days to 3 hours
 - Utilizing functionalized gold nanoparticles to detect nucleic acid or protein targets
 - Multiple other tests under development with more accurate, more specific results
- Spun out of Northwestern University (Illinois, USA) in 2000
 - US\$5 million in revenues in 2012
 - Approximately US\$300 million invested since founding
 - Currently scaling up manufacturing facilities
 - Initial Public Offering (IPO) on the NASDAQ in 2007
 - Market capitalization of US\$155 million in 2013

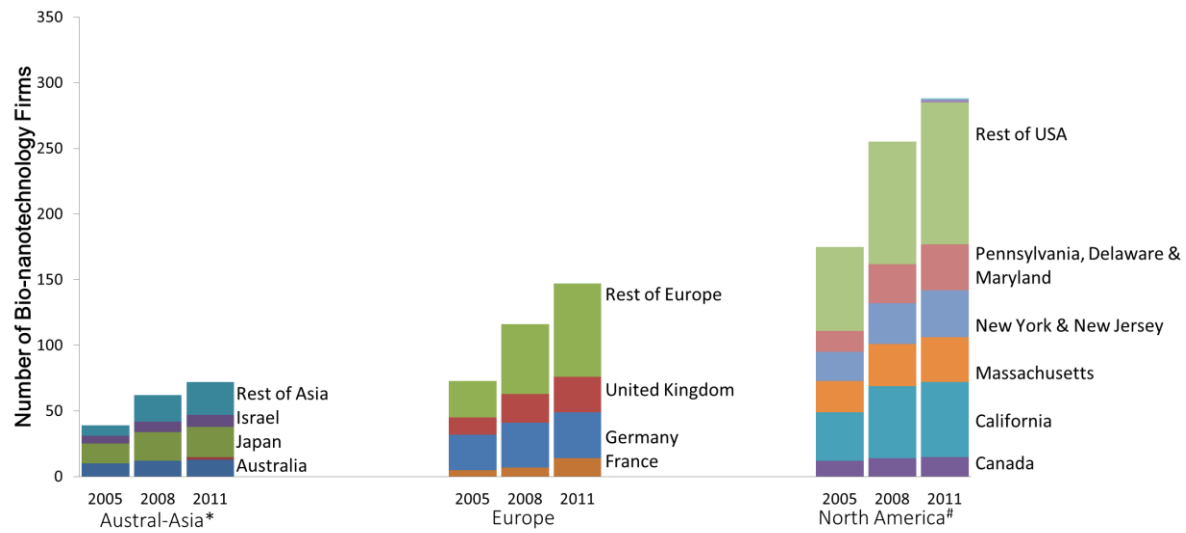


Figure 2: Evolution of the Global Bio-nanotechnology Industry by Regions

*Asian countries as well as Australia, New Zealand and Israel.

North America includes USA, Canada and 3 South American firms which entered in 2011.

Table 1: Global Distribution of Bio-nanotechnology Firms

| Cohort/ Region | Austral-Asia* | Europe | North America[#] | Total |
|-----------------------|----------------------|---------------|----------------------------------|--------------|
| 2005 | 39 | 73 | 175 | 287 |
| 2008 | 62 | 116 | 255 | 433 |
| 2011 | 72 | 147 | 288 | 507 |

*Asian countries as well as Australia, New Zealand and Israel.

North America includes USA, Canada and 3 South American firms which entered in 2011.

Table 2: Bio-Nanotechnology Industry Subsectors

| Bio-Nanotechnology Industry Subsector | Definition | Example Firms¹ |
|--|--|---|
| Biopharmaceuticals | Firms involved in multiple sub-segments such as pharmaceuticals, drug delivery, contract research. | Roche, Merck, Bayer, Johnson & Johnson, DuPont, Celator |
| Drug Delivery | Firms specializing in drug delivery | C-Sixty, enGene, 3M, Siemens |
| Diagnostics | Firms specializing in human diagnostics and imaging | NanoSphere, NanoGen, PanBio, NanoProbes |
| Suppliers & Instrumentation | Firms supplying nano-materials, instrumentation, consumables, lab equipment | Dow, Degussa, Agilent, Toray, Hitachi |
| Medical Devices | Firms providing medical devices such as wound care products, blood care products etc. | Wilson Greatbatch Inc, Haemonetics |
| Biomaterials | Firms focussing on dental implants, orthopedic implants etc. | Allvivo Vascular, Mnemo Sciences, Nanovis |
| Bioinformatics | Firms specializing in bioinformatics and providing drug discovery services. | HP, IBM |

¹ We classify multinational corporations (MNCs) based on their applications in the bio-nanotechnology space. For example, 3M's bio-nanotechnology focus is on asthma inhaler innovation and thus 3M is classified in the drug delivery subcategory.

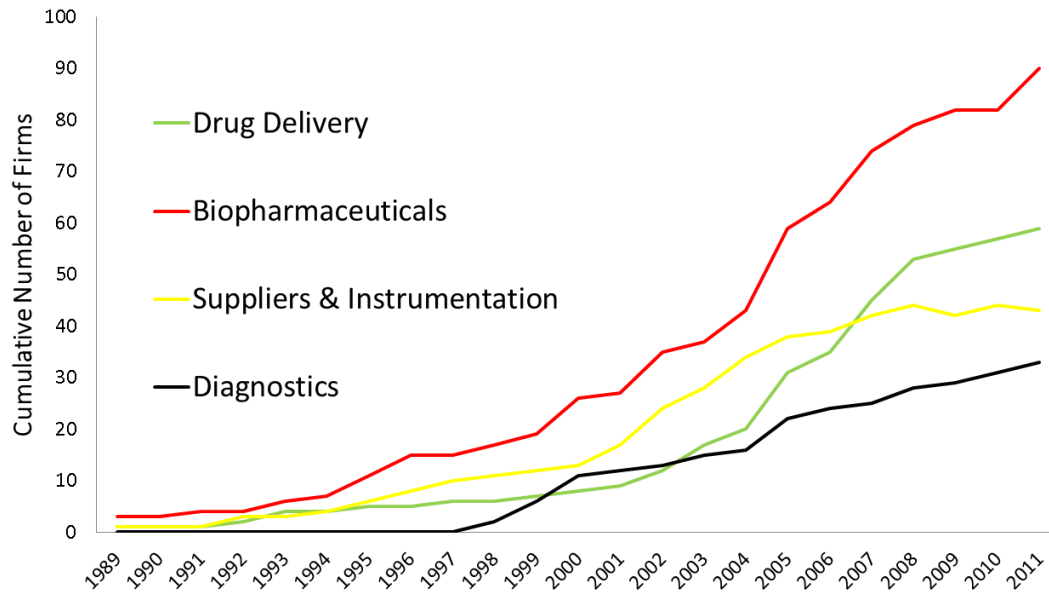


Figure 3: Evolution of Selected Bio-Nanotechnology Subsectors in the USA

Supplemental Material for The Emergence of the Bio-Nanotechnology Industry:

Methods

We created three distinct samples (cohorts) for longitudinal analysis over the course of evolution of the bio-nanotechnology industry: these cohorts consist of those firms with both biotechnology and nanotechnology capabilities as of 2005, 2008 and 2011. We used the DMS

IndustryAnalyser, DMS NewsAnalyser, and Medtrack databases to identify a pool of firms which potentially held both biotechnology and nanotechnology capabilities, whether integrated or in separate research divisions. DMS IndustryAnalyser and DMS NewsAnalyser went out of service in 2009, necessitating the use of a new database to create the 2011 cohort. Relevant firms from the 2011 cohort were added to the earlier cohorts, creating a robust sample.

Similarly, firms identified by DMS in the 2008 cohort (but not by Medtrack) were added to the 2011 sample, when proof was found that they still had relevant capabilities.

Next, we verified the existence and timing of development of both sets of capabilities through web searches, press releases, publications, and US patents. Nanotechnology patents were identified using keywords adapted from recent studies^{1,2} and biotechnology patents were identified using standard guidelines based on patent sub-classes³. Using the patent filing date from the first of the selected patents and comparing with the founding year of the firm, we were able to classify firms as de novo if the difference between the founding year and year of acquisition of nanotechnology capability was 3 years or less. Firms with more than 3 years difference between founding and year of acquisition of nanotechnology capabilities were identified as de alio or incumbent firms. In cases where firms had not yet had patents assigned to them, press releases, company documents, scientific publications and industry reports were used

to identify the initial year of development of nanotechnology capabilities. These additional data sources allowed us to retrospectively supplement each cohort if these sources indicated such capability development prior to their date of entry in the three databases used. This retrospective analysis thus enables our sample to comprehensively represent the evolution of this industry. We acknowledge that there may have been some exits prior to 2005 which would not necessarily have been captured by our methodology.

Patent data also was used as a measure of the level of integration of biotechnology and nanotechnology capabilities within a firm. We gathered all biotechnology and all nanotechnology US patents issued by the firms in our sample and identified patents overlapping both searches. As of 2011, 82 firms out of the 507 bio-nanotechnology firms in our global sample had issued US patents which integrated biotechnology capabilities with nanotechnology capabilities. The level of bio-nanotechnology integration was higher in de novo firms than in multinational corporations.

By treating all firms as fundamental experiments in the evolution of an emerging industry and by attempting to capture all firms in the industry over time, our study adds to existing industry evolution literature by studying a case of technology confluence as it unfolds. Our advancement in granularity includes tracking firm entry and exit, firm type, and application focus. Using data from company documents, industry reports and the DMS and Medtrack databases, we are able to classify the biotechnology firms as belonging to specific sub-sectors which helps us to examine the evolution of bio-nanotechnology at the level of the sub-sector. Previous studies have concentrated on bibliometric assessments of scientific publications or patents to separately examine the biotechnology and nanotechnology industries⁴, or to examine

specific case studies within the bio-nanotechnology industry regarding the generation of interdisciplinary knowledge⁵. Patents, while critical to the study of invention, do not adequately represent innovation. One study which did examine firms commercializing nanomedicine identified 207 firms globally as of 2004: the study focused on new products which had been enabled by micro- and nanotechnology⁶. A later study identified 308 medical nanotechnology firms as of 2007⁷.

We extend existing studies in several ways. First, we focus on tracking the entry of firms into the emerging bio-nanotechnology industry, and are very comprehensive in our identification of global bio-nanotechnology firms, resulting in a broader geographical distribution than found in previous studies. Second, we also are more specific to nanotechnology by limiting our inclusion criteria to firms with nanoscale capabilities defined as less than 300 nm, as opposed to the 1000 nm criteria utilised by the earlier studies^{6,7}. Third, we are inclusive of bio-nanotechnology firms which do not yet have issued patents, where there is other public evidence of both biotechnology and nanotechnology capabilities. Fourth, by adopting keywords used to search broadly for nanotechnology patents^{1,2}, while also tracking all firm biotechnology patents, we are able to enhance our industry evolution analysis and also provide insight on integration of biotechnology and nanotechnology capabilities. Together, this approach enables us to contribute a nuanced, comprehensive picture of the evolution of the global bio-nanotechnology industry.

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