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Letter from the Editor

Preparing for the time after the crisis

The thunderstorms that have struck economy (Vol. 6, Iss. 2) are becoming less. Currently, it is believed that we have reached the bottom of the economic recession. There are rays of hope blazing at the horizon, which will hopefully be the precursor of sunlight again. Nevertheless, experts dun the public not to be too optimistic again. The crisis is not over yet and its consequences cannot be foreseen completely. However, those companies not standing at the edge of bankruptcy are already preparing for post-crisis business. Once the own processes have been optimized, future strategic alignment becomes one of the main tasks to make oneself as invulnerable as possible for the next downturn. Thus, working on the new major trends like increasing energy costs, aging population or increasing global environmental awareness provides great opportunities. Especially the chemical industry is in the front line here to drive these developments. Therefore, the third issue of the Journal of Business Chemistry sheds light on various aspects of these developments:

In his commentary "A capital market's view on Industrial Biotechnology", Bernd Schneider takes a look at White Biotechnology and its perception at the stock markets. Especially concerning the latter, the author compares White Biotechnology with its red counterpart. Finally, he gives an outlook on the future of Industrial Biotechnology.

The contribution to the Research Section provides a systematic approach for obtaining an overview of a large amount of selected patents. In their article "Assessment of thermal-stable polymer nanocomposite techniques by patent citation network analysis", Hsin-Ning Su and Pei-Chun Lee use basic patents statistics, technology-function and standard industrial classification. Adding patent citation and network properties calculation, they bridge the gap between patented techniques and business management activities.

Kaisa Soirinsuo, Elina Kähkönen, Jouko Karjalainen and Katrina Nordström present a study that evaluates the need for new Active Ingredient development. In their article "Feasibility of Active Ingredient (AI) development for new biocides in the EU", the authors take a closer look at the effects of EU regulations on future market opportunities of biocides.

Finally, Jürgen Peukert and Thomas Fuggenthaler discuss the possibility of pharmaceutical companies to supply even poor parts of the globe with medicinal products. In their contribution "How to implement 'access to medicine' AND enhance economic performance", the authors argue that this socially desirable project can also be beneficial from the economic point of view.

Concurrently with the preparations for the third issue, we revised and relaunched our website to follow the recently revamped print layout. Both versions (print and web) of the JoBC are now going hand in hand again. The new homepage does not only convince with its appearance but also with new features. Among others, the search function now enables the reader to look for keywords in all articles. We hope that the new website will improve your convenience reading the JoBC. Finally, we want to thank the German Research Foundation (DFG) for their financial support, which gave us the opportunity to initiate and complete this project.

Now, please enjoy reading the third issue of the sixth volume of the JoBC. We would like to thank all authors and reviewers who have contributed to this new issue. If you have any comments or suggestions, please do not hesitate to send us an email at contact@businesschemistry.org.

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Commentary

A capital market's view on Industrial Biotechnology – proper valuation is the key for picking the right investment opportunities in stormy times

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Introduction

Industrial biotechnology, also known as white biotechnology, is considered to be a revolutionary biotechnology field beside red and green biotechnology. After red (medicine) and green (agriculture), white biotechnology is now gaining momentum. With numerous applications e.g. in biocatalysis and fermentation technology, white biotech companies are able to produce – often from biomass out of agricultural products - biobased chemicals (like vitamins, amino acids or enzymes for textile finishing and the detergent industry), biomaterials (like biodegradable plastics for packaging or medical applications) and biofuels. Biotechnological syntheses are supposed to revolutionize many classical chemical synthetic routes for established chemicals and will outpace those by higher cost-efficiency, saving feedstock and energy resources and offering valuable benefits to the environment by lower or even no greenhouse gas emissions.

The Capital Market's Perception – White versus Red

Whereas Red Biotechnology is already accepted by the capital markets and dominates by far the total number of biotechnology companies, there are only few dedicated white biotech companies. Venture capitalists have preferred red opportunities, while white biotechnology used to have a lower attendance with capital markets and is still more driven by big chemical corporations than an agile start-up scene. The focus of red biotech is on new drugs with a relatively easy to estimate market potential and share, while industrial biotechnology mainly develops new process routes to already known drugs or chemicals. These characteristics require more knowledge of the industry and often contribute to the lack of investors' attendance of white versus red biotechnology. In comparison to red, white biotech processes or products usually serve a broader range of applications and should thus diversify the investor's risks accordingly. However, many venture capitalists still are not aware of the chances or even seem to shy away from taking the white opportunity, presumably because of difficulties in reasonably estimating the scope of market potential and market share that could be achieved with a single process or product. However, the impact of white biotechnology can be found in most future oriented statements of big chemical companies and is expected to drive future chemicals earnings significantly. Furthermore, the number of spin-offs from universities and start-ups with a dedication on white biotech is expected to pick up momentum. Investors conferences are held with dedication on white biotech companies and investors are more and more looking for this emerging sector. All this makes it obvious that now could be the time to look for opportunities for paying-off investments.

The adequate valuation of investment opportunities in growth companies within industrial biotechnology is, though, often

seen as a challenge by market participants. Principally, several techniques are available for valuing white biotech companies: The DCF method, the Multiples valuation, Venture Capital method, the Portfolio or Sum-Of-The-Parts approach or option based valuation techniques like the Real Option valuation. Admittedly, it can be tricky to put a price tag on biotechnology companies that often offer little more than the promise of success in the future. Just because someone in the lab cries "Eureka!", that doesn't necessarily mean that a revolutionary process or enzyme has been found. In the biotech sector, it can take many years to determine whether all the effort will translate into returns for a company. Red biotechnology is a forward-looking, cash-hungry industry. Sometimes, it takes far beyond a billion of Euros and many years to develop a drug which then might not come to market. So biotech and pharma companies are constantly looking to all areas of the finance industry for funding. Their assets are often highly intangible (intellectual property) and, because they are so forward-looking, there is little current concrete information available for the investor other than retrospective insights into previous projects. It is a high-risk business, but one which can give massive returns. In comparison to red, white biotech investments often afford lower initial investments and offer lower risk due to a diversification among applications and industries. Two of the characteristics of white biotech, to which investors are giving increasing attention, are the typically much shorter time span from idea to market – 3 to 5 years, compared to 10-12 years for a biomedical product – and less regulatory requirements. The accumulated market potential, market shares and derived free cash flows are, however, more complex compared to red biotech projects and can require the engagement of several industry specialists. Industry teams that are engaged in the valuation can comprise biotechnology specialist, chemicals and consumer good or medical applications expertise. Despite the complexity of deriving a value from white biotechnology projects, the business models are often highly promising and many white investment opportunities, that are currently undiscovered, wait to be caught. For picking the right alternative, investors need to be able to evaluate such companies properly in order to make proper business decisions about their investment. The credit crunch increases the need for the proper valuation approach in general, but in particular for the high-risk biotechnology sector: Due to the credit crunch, the European Biopharmaceutical Enterprises trade association reckons that 20% of all European biotech companies could go out of business in the next six to 18 months (Warmington, 2009). Comparatively, this could mean another chance for white biotechnology to increase attention due to eventually more stable business models and broader application ranges.

A Glimpse into the Future of White Biotechnology

Although reality could not come up with the forecasted impacts of white biotech on traditional chemical production processes, it is more a question of when but if the revolution will happen (EuropaBio, 2003). The development and use of Industrial Biotechnology is therefore essential to the future competitiveness of European industry and provides a sound technological base for the sustainable society of the future.

In the long run, it is undoubted that an increasing number of chemicals and materials will be produced using biotechnology in one or more of the processing steps. Biotechnological processes will be used to produce chemicals and materials which are hard or impossible to produce or – more frequently - make existing products in a more efficient way. Biotechnology will allow increasingly eco-efficient use of renewable resources as industrial raw materials. Rural bio-refineries can replace port-based oil refineries wherever it is economically feasible. Industrial biotechnology will enable a range of industries to manufacture products in an economically and environmentally sustainable way.

Furthermore, biomass-derived energy based on biotechnology is expected to account for an increasing share of European energy consumption. European industry will be innovative and competitive, with sustained cooperation and support between the research community, industry, agriculture and civil society. Green biotechnology will make a substantial contribution to the efficient production of biomass raw materials and green and white biotechnology will thus combine to an integrated value chain. The prospects will, however, only become

reality with the appropriate enabling political and economical environment stimulating research and innovation, entrepreneurship, product approval and market development. As long as the cost of fossil fuel and feedstock for key chemicals have not passed their respective critical thresholds, industrial biotechnology and its products will need political support and funding, particularly in the energy and bulk-chemicals sectors. Other uses of industrial biotechnology, however, such as biocatalytic conversions of fine and specialty chemicals and the manufacture of high-value products, such as nutraceuticals, cosmeceuticals and performance chemicals offer dynamic growth opportunities both for established chemical industries, as well as emerging entrepreneurial enterprises. Attracting venture capital (VC) will remain a challenge in the short and medium term particularly for white biotech companies due to VC firms shying away from cyclical businesses and risks that have not been made transparent sufficiently by the biotech's management. Furthermore, VC firms need a vision on the appropriate exit pathways. They often stay onboard for about four to eight years and look for IPOs or trade sale to big chemicals companies. In comparison to the red alternative, there is little evidence on the IPO or M&A history with respect to industrial biotech targets.

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Research Section

Assessment of thermal-stable polymer nanocomposite techniques by patent citation network analysis

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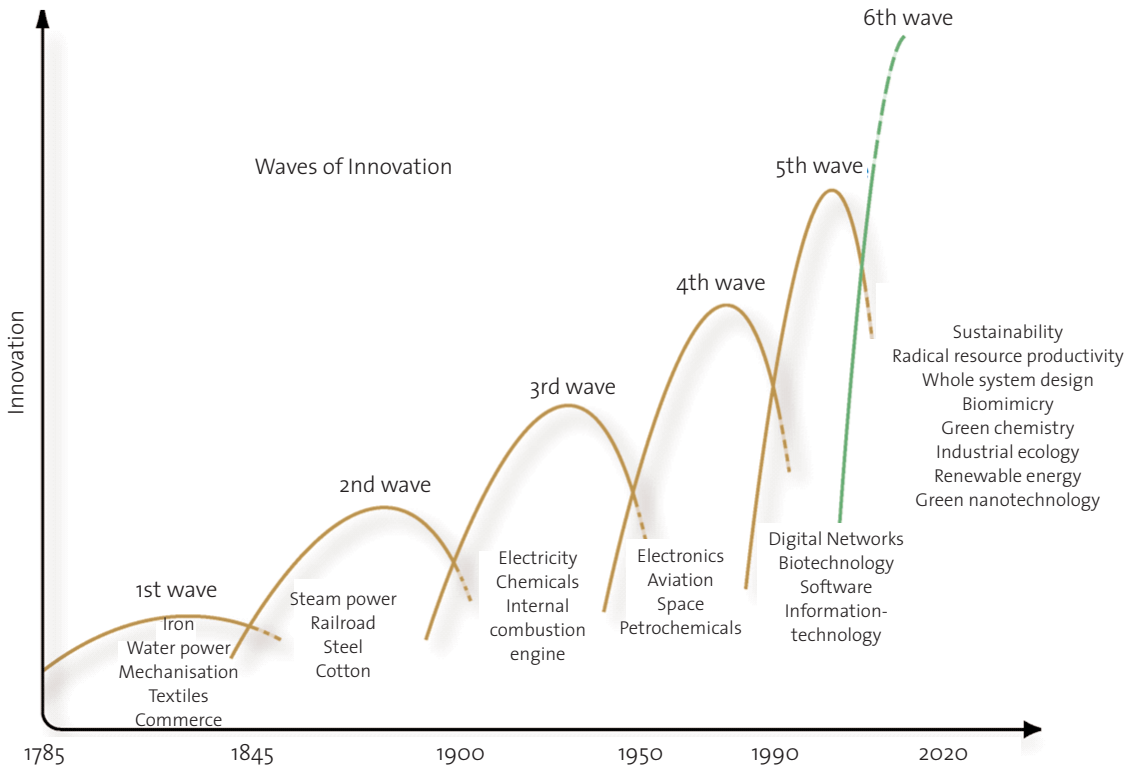
Nanocomposite material with new functions or properties superior to traditional composite materials opens a door to transform the way that material is currently applied. This study aims to provide 1) a systematic and quantitative method for obtaining global patent overview, 2) a global patent-citation overview on thermal-stable polymer nanocomposite patents retrieved from the United States Patent and Trademark Office (USPTO). The systematic method provided in this paper is integration of basic patent statistics, technology-function classification, standard industrial classification, patent citation and network properties calculation. All of these contribute not only to a systematic approach for obtaining a quantitative overview of large amount of selected patents, but also bridge the gap between patented techniques and business management activities, e.g. R&D resource allocation, performance evaluation, patent map visualization, patent valuation, in business and industry.

Introduction

Intellectual property has become more and more important for competitive advantage in modern society and it is generally believed that intellectual property is a critical and fundamental factor for future business success. Companies which try to ensure their intellectual properties file patents to protect their inventions in order to define technical areas from where they are able to generate profits. Companies or industries which try to optimize and manage their patent portfolios (Friese et at., 2006) which can substantially lead to benefits such as market monopoly position, revenue from licensing the intellectual property, and innovation strategies advanced by patents. However, patent management, particular for managing large number of patents, not only leads to monetary benefits but also provides way of implementing development strategy by positioning patents in a patent map. The patent map allows evaluation of patent value, search for potential collaboration partners and benchmarking comparison, etc. A question raised here is-How to manage a large number of patents and obtain a quick overview of a large number of patents?

In order to answer this question, this research proposes a systematic process beyond conventional patent statistics for patent trend analysis (Suárez et al., 2005) and allows business and industry to analyze and evaluate patented techniques by integrating basic patent statistics, technology-function classification, standard industrial classification, patent citation and network properties calculation. All of these contribute to a systematic approach for obtaining an overview of large amount of selected patents. More importantly, this paper provides a quantitative way of evaluating patents and thus a computerized calculation is possible for potential quantita-

Figure 1 Waves of Innovation (Hargroves and Smith, 2005)



tive applications such as R&D resource allocation, research performance evaluation, patent map visualization, patent valuation, etc.

Mapping knowledge evolution by bibliometric analysis

Thomas Kuhn published "The structure of scientific revolution" (Kuhn, 1970) and popularized the terms "paradigm" and "paradigm shift". Dosi (1982) investigated technology trajectory on the basis of paradigm shift and found continuous innovation can be regarded as proceeding of technology paradigm, while discontinuous innovation might be the initiation of a new paradigm. The differentiation between continuous innovation and discontinuous innovation may be positive for understanding initiation of a new paradigm as well as position and diffusion of a specific technology or knowledge. For example, Figure 1 shows six waves of Sci-Tech innovation between 1785-2020, which can also be regarded as six paradigms, proposed by Hargroves and Smith (2005). A continuous innovation is what happened in the same wave, while discontinuous innovation is the jump from one wave to the next wave.

A lot of methodologies have been proposed and applied into various knowledge fields for understanding their technology development overview. For example, Pouris and Pouris (2009) made international comparison on biotechnology research to identify potential strategies and policies for South African biotechnology innovation system. However, what usually used for this purpose is bibliometric analysis on patents or scientific papers by way of classifying papers or patents into different categories along time horizon. In this case, understanding of relations among papers or patents is not possible, and hence advanced applications based on paper relations, e.g. identify potential research partnership, identify which paper/patent is important, cannot be approached.

To solve the issue of paper/patent relations identification, attempts have been made by the use of keyword as a bridge of connecting paper/patents, so keyword based analysis as a type of co-word analysis (King, 1987; Law and Whittaker, 1992) started to play an important role in understanding the dynamics of

knowledge development. (Gupta and Bhattacharya, 2004). Ding et al. (2001) mapped information retrieval research by using co-word analysis on papers collected from Science Citation Index (SCI) and Social Science Citation Index (SSCI) for the period of 1987–1997. Baldwin et al. (2003) mapped ethics and dementia research by using keywords. Tian et al. (2008) used ISI database to measure scientific output of the field of GIS (Geographic Information System) by using keywords.

However, a lot of literatures used the above mentioned keyword-based analysis providing less sense of knowledge accumulation over time or limited understanding on causal interpretation of human knowledge development. Therefore, this study aims to use the alternative citation based method to avoid this problem and reap reward from the well-assigned citations in structured patent documents for drawing an overview of how a selected technology field, thermal-stable polymer nanocomposite technology, is evolved. Nanocomposite has been a popular material that is defined as multiphase solid material where one of the phases has one, two or three dimensions of less than 100 nanometers (Manias, 2007), and polymer nanocomposite is a type of nanocomposites that contains at least one polymeric phase (Mai and Yu, 2006). The research target set in this study is a type of polymer nanocomposite materials capable of being thermally stable (Morgan and Wilkie, 2007). The dynamic overview of knowledge evolution for this selected field is investigated in this paper.

Mapping technology network by patent citation

It has long been a very critical part of human knowledge system that patent and scientific publications are two most significant ways of disclosing science and technology progress in this society. Former publications can be served as important references or bases for later publication, in this way human knowledge can be gradually accumulated to sustain and expand knowledge system. The important featuring characteristic of patent and scientific publication for knowledge accumulation is their citations showing which former literatures have contributed to later paper/patent and providing the context of knowledge acumulation. A number of researches have noted that patent citations trace out technological building relationships among inventions (Jaffe, Trajtenberg and Henderson, 1993). Also, citation has been widely used in bibliometric study to evaluate technology development, research performance, and even map knowledge evolution or technological trajectory. For instance, Acosta (2003) investigated the links between science and technology based on an analysis of scientific citations in patent documents to study in greater depth the relationship between science and technological development in various regions of Spain, Hall et al. (2000) suggested that of all patent related indicators, patent citation is a more adequate indicator to evaluate market value, Stuart and Podolny (1996) used patent citations to measure firms' technological niches and niche shifts.

Otte and Rousseau (2002) studied citation network, utilized as a type of social interaction networks, by the use of social network analysis, and calculate network property to discover how information can be disseminated among network actors, and Liebowitz (2005) indicated the possibility of mapping knowledge flows and measuring relationships among actors in a network. Accordingly, this research aims to shed light on identifying critical patents by the use of social network analysis, patent citation information allows the building of patent linkages which eventually leads to a citation network as a whole. The constructed patent citation network, with patents as network nodes (actors) and patent citation as network ties, allows quantitative analysis on patent citation network by calculating network properties, e.g. Degree Centrality, Betweenness Centrality, and Closeness Centrality. In this sense, mechanism of knowledge flow or technology evolution mechanism, e.g. technology convergence, technology diffusion, etc. can be quantitatively analyzed.

Research Method

Initial patent sampling

This research selects nanocomposite material as research target to draw its citation network. Patents with “nano” and “composite” appeared in title or abstract of patents in application are retrieved from USPTO (Patent retrieval time: Jun. 11, 2008). The retrieved patents are carefully reviewed to remove those which are not sufficiently related to nanocomposite material, and finally a total of 672 patents are remained as our target patents named as “ini-

tial patent" in this study.

The development of technology-function matrix

The obtained 672 patents are critically analyzed and classified into two dimensions, 1) technological dimension based on the matrix material disclosed in patents, i.e. polymer, clay, ceramic, metal and other, 2) functional dimension based on the function of invented techniques, i.e. mechanical and dimensional stability, permeability, thermal stability, flame retardancy, chemical resistance, surface appearance, electrical conductivity, optical and light emitting property, cement/adhesivity, magnetic property, and other, as shown in Table 1. Validation is done by comparing the content of classified patents with multiple sources and through informal interviews with members of our expert panel. It is worth noted that one single patent may disclose more than one matrix material or more than one function, so one patent can thus be categorized into more than one classification and thus the total patent count in Table 1 is 824 instead of original patent count of 672. The classification of "other" in both matrix and function in Table 1 are either for patents disclosing some other materials or functions that are not considered in this study, or patents trying to reduce the specificity of its disclosed matrix or function by disclosing more than three matrix materials or or functions. The obtained technology-function matrix shown in Table 1 provides an overview, or a so-called "patent map", for the development of nanocomposite material. Subsequently, this research selects 70 patents with the technology of "polymer" matrix and function of "thermal stability" to meet the requirement of the research target set in this study.

Network patent sampling

After classification of technology and function, the 70 patents with polymer matrix and function of thermal stability are used as primary patents based on which their backward citation patents and forward citation patents are retrieved from USPTO database as the secondary patents which are upstream patents and downstream patents of the primary patents, respectively. By examining upstream and downstream patents, a technological context of what upstream patents contribute to primary patents and what downstream patents are contributed by primary patents can be understood and the underly-

Table 1 Patents Classification on the basis of material and functions

		MATRIX MATERIAL					
		Polymer	Clay	Ceramic	Metal	Other	Total
FUNCTION	Mechanical and dimensional stability	176	4	59	35	11	285
	Permeability	52	1	1	0	1	55
	Thermal stability	70†	1	16	13	3	103
	Flame retardancy	19	0	0	0	1	20
	Chemical resistance	17	0	5	4	4	30
	Surface appearance	6	0	2	0	1	9
	Electrical conductivity	69	0	28	30	21	148
	Optical and light emitting property	77	0	19	10	15	121
	Cement/adhesivity	7	0	1	0	0	8
	Magnetic property	10	0	7	28	0	45
	Other	56	2	20	19	23	120
	Total	**503**	**6**	**138**	**120**	**57**	**824**

† Research target selected in this study.

ing knowledge flows can thus be analyzed. In summary, this research uses 1) primary patents: the 70 patents with polymer matrix and function of thermal stability, 2) secondary patents: 558 backward citation patents of the 70 primary patents and 543 forward citation patents of the 70 primary patents, as actors of the technology network (patent citation network) to be drawn in this study. The total number of obtained patents is 1,069 instead of 1,171 (the sum of primary patents and secondary patents) after removal of duplicated count (some patents belong to both primary and secondary patents). The 1,069 patents are defined as "network patents" and are therefore treated as network actors (node). Along with the network ties built by patent citation linkages, a technology network for understanding the developed context of thermal-stable polymer nanocomposite can be achieved.

Patent citation network and network property calculation

After construction of the technology network, network property is subsequently calculated. In social network theory, "Centrality" is a key network property to estimate how easy an actor retrieves or controls resources from the network. Freeman (1979) proposed three ways of measuring network centrality, Degree Centrality, Betweenness Centrality, and Closeness Centrality. The higher centrality indicates more associations with actors in a network. Brass and Burkhardt (1992) pointed out the higher centrality of a person in a social network, the more power s/he possesses from the viewpoint of organizational behavior. This research also uses the three ways of measurement for obtaining centrality of patented technology, in order to understand importance, influence, diffusivity and convergency of a patented technology.

Degree Centrality

Network nodes (actor) which directly linked to a specific node are neighborhood of that specific node. The number of neighbors is defined as nodal degree, or degree of connection. Granovetter (1973) suggested nodal degree is proportional to probability of obtaining resource. Nodal degree represents to what degree a node (actor) participates the network, this is a basic concept for measuring centrality.

(i) InDegree Centrality: the number of time that patent i is cited by other patents. The higher InDegree Centrality, the more times that patent i is cited, the higher momentum of knowledge diffusion from patent i to other patents.

$$In\_Degree(i) = \sum_j m_{ji}$$

m_{ji}=1 if patent i is cited by patent j

(ii) OutDegree Centrality: the number of times that patent i cites other patents. The higher OutDegree Centrality, the more times that patent i cites other patents, the higher momentum of knowledge convergence from other patents to patent i.

$$Out\_Degree(i) = \sum_j m_{ij}$$

m_{ij}=1 if patent i cites patent j

Betweenness Centrality

The concept of betweenness is a measure of how often an actor is located on the shortest path (geodesic) between other actors in the network. Those actors located on the shortest path between other actors are playing roles of intermediary that help any two actors without direct contact reach each other indirectly. Actors with higher Betweenness Centrality are those located at the core of the network.

$$Betweenness(i) = \sum_{j,k \neq 1} \frac{g_{jik}}{g_{jk}}$$

g_{jk} shortest path between patent (actor) j and patent k

g_{jik} the shortest path between patent j and patent k that contains patent i

Closeness Centrality

The Closeness Centrality of an actor is defined by the inverse of the average length of the shortest paths to/from all the other actors in the network. Higher Closeness Centrality indicates higher influence on other actors. In a directed network, Closeness Centrality can be divided into InClosenesss Centrality and OutCloseness Centrality.

(i) InCloseness Centrality: the shortest path from other patents to patent i, the higher InCloseness Centrality, the higher influence of patent i on other patents.

$$In\_Closeness(i) = \sum_{j=1}^{N} \frac{1}{d_{ji}}$$

d_{ji} the shortest path from patent j to patent i

(ii) OutCloseness Centrality: the shortest path from patent i to other patents, the higher OutCloseness Centrality, the easier for patent i to be influenced by other patents.

$$Out\_Closeness(i) = \sum_{j=1}^{N} \frac{1}{d_{ij}}$$

d_{ij} the shortest path from patent i to patent j

Concordance between network properties and technology evolution mechanisms

The previously mentioned network properties can be used as indicators for characterizing technology evolution context, and therefore quantitative analysis on the evolution context can be obtained. In this study, we propose the applications of the five network properties on evaluating evolution contexts for thermal-stable nanocomposite technology, namely the concordance between network properties and technology evolution mechanisms, which provides a quantitative approach toward evolution mechanism:

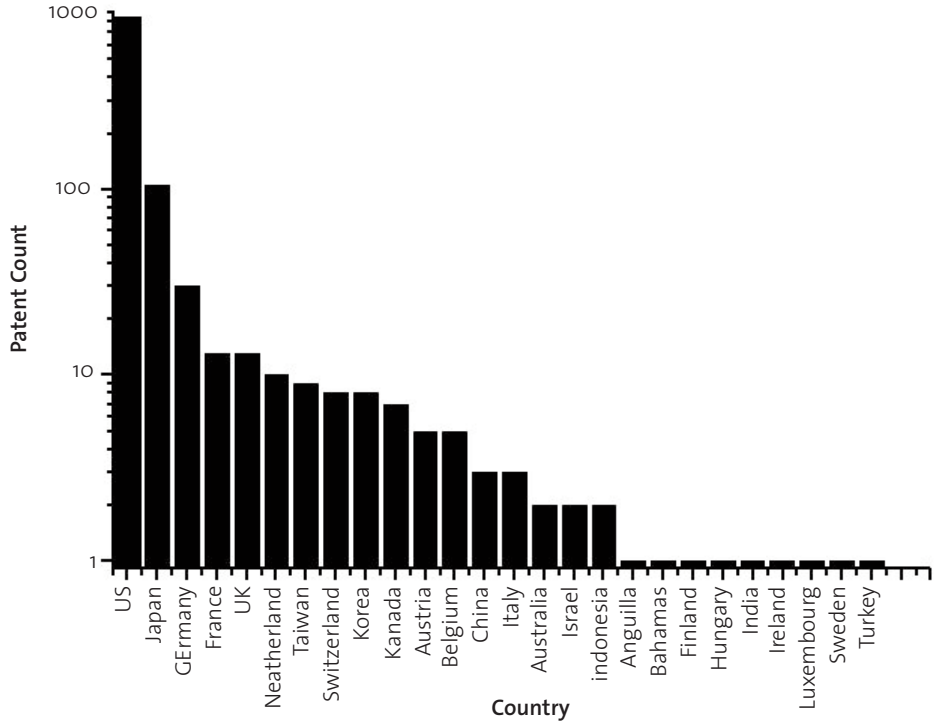
(i) InDegree Centrality: the number of times that a patent is cited, it can be used as an indicator to measure knowledge flow from one target patent to later patents. Because of its implication of knowledge diffusion, InDegree Centrality is defined as an indicator to measure momentum of technology diffusion.

(ii) OutDegree Centrality: the number of times that a patent cites other patent(s), it can be used as an indicator to measure knowledge flow received by a target patents. Because of its implication of knowledge convergence, OutDegree Centrality is defined as an indicator to measure momentum of technology convergence.

(iii) Betweenness Centrality: how often an actor is located on the shortest path (geodesic) between other actors in the network. Therefore, Betweenness Centrality is defined as an indicator to measure momentum of technology transition.

(iv) InCloseness Centrality: the shortest path

Figure 2 Patent count by countries



from other patent(s) to a target patent. The shorter path, the stronger the target patent influences other patent(s). InCloseness Centrality is therefore defined as an indicator to measure momentum of influence.

(v) OutCloseness Centrality: the shortest path from a target patent to other patent(s). The shorter path, the stronger the target patent is influenced by other patent(s). OutCloseness Centrality is therefore defined as an indicator to measure momentum of being influenced.

Even though the five network properties represent five mechanisms of technology evolution. Patents with higher centralities are those located closer to the core of a target research field, or they can be called the core patents. But the idea of "core" relies on which of the five above indicators is used.

Results and Discussion

Initial patent analysis

According to the technology and function matrix shown in Table 1, in terms of technology, most patents disclosed nanocomposite material with polymer matrix (503 patents) and subsequently ceramic matrix (138 patents). In terms of function, most patents are for mechanical and dimensional stability (285 patents), and then electrical conductivity (148 patents), optical and light emitting property (121 patents). This research aims to study thermal-stable polymer nanocomposite, so the 70 patents with technology of "polymer" matrix and function of "thermal stability" are selected as primary patents for subsequent investigation.

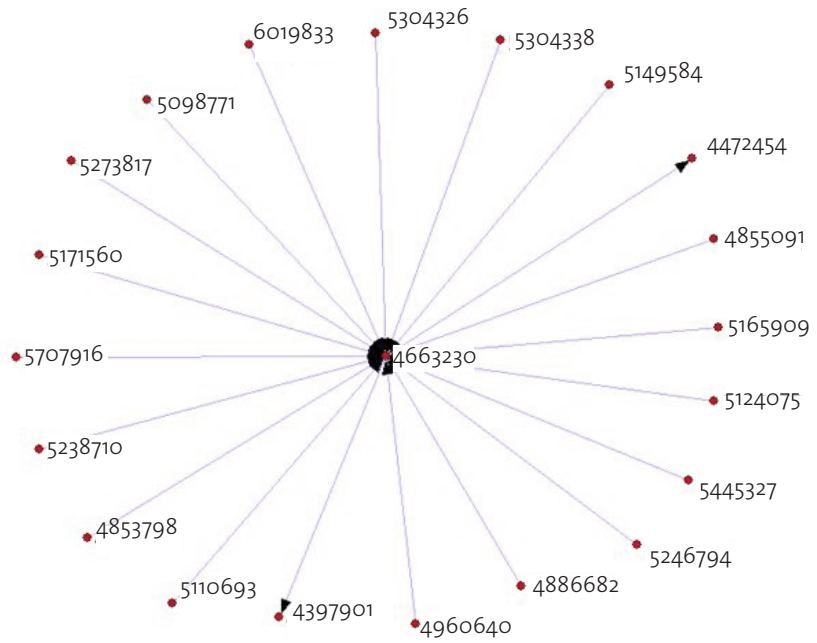
Network patent analysis

For all the obtained 1,069 network patents, countries with most patents are the US (846 patents), Japan (105 patents), Germany (30 patents), France (13 patents), UK (13 Patents) and Taiwan (7 patents). This revels thermal-stable polymer nanomposite related technologies are mainly located in the US, Japan, and Europe but the US is much more significant than other countries, Figure 2.

Table 2 Top 20 Standard Industrial Classifications for 1,069 network patents

Ranking	Standard Industrial Classification (SIC)	SIC Code	Patent Count
1	Paints, varnishes, lacquers, enamels, and allied products	285	295
2	Rubber and miscellaneous plastics products	30	147
3	Industrial inorganic chemistry	281	95
4	Miscellaneous chemical products	289	81
5	Plastics materials and synthetic resins	282	71
6	Professional and scientific instruments	38, except 3825	57
7	Stone, clay, glass and concrete products	32	49
8	Textile mill products	22	43
9	Industrial organic chemistry	286	43
10	Electronic components and accessories and communications equipment	366-367	31
11	Drugs and medicines	283	26
12	Electrical industrial apparatus	362	17
13	Agricultural chemicals	87	16
14	Fabricated metal products	34, except 3462, 3463, 348	15
15	Miscellaneous electrical machinery, equipment and supplies	369	14
16	All other SIC's	99	12
17	Special industry machinery, except metal working	355	9
18	General industrial machinery and equipment	356	9
19	Petroleum and natural gas extraction and refining	13, 29	8
20	Farm and garden machinery and equipment	352	8

Figure 3 Patent citation network for thermal-stable polymer nanocomposite between 1936-1992.



The 1,069 network patents are classified by Standard Industrial Classification (USPTO UPC to SIC concordance, 2008), as shown in Table 2, there are 295 patents in No. 1 classification (paints, varnishes, lacquers, enamels, and allied products), and 147 patents in No. 2 classification (rubber and miscellaneous plastics products). The sum of No. 1 and No. 2, paints and plastics related, are more than one third of the total 1,069 network patents. This possibly implies the incorporation of nanoparticle into polymer matrix are major technologies to obtain nanocomposite material and conventional painting, resin, plastic industries are easier to be involved in both nanotechnology and composite fields.

Patent citation network analysis

Overall network

The patent citation network composed of 1,069 patents and 2,318 patent citation relationships are plotted by computer, shown in Figure 3-5 for patents filed on different time period (Note: patents which act as isolated node/actors without any networking behavior are not shown in the figures). Each node represents a patent and each network tie with arrow represents a citation relationship. The patents pointed by arrows of the network ties are cited by those patents located at the other end of the network ties. In Figure 3, citation network based on patents filed in the period of 1936-1992 is plotted and only several patents are networked together and presented a simple radial structure. In Figure 4, more patents are networked together for the period of 1936-2000 but still several separated clusters can be observed. In Figure 5, networking is fully matured and almost all patents are networked together for the overall time period of 1936-2007 in this study.

Network properties calculation

According to aforementioned method of calculating network properties, network properties, i.e. Betweenness Centrality, InCloseness Centrality, OutCloseness Centrality, InDegree Centrality and OutDegree Centality of each network node are calculated. Figure 6 shows the average of Betweenness Centrality, OutDegree Centraliy and InDegree Centrality for each year. Significant peaks around the period of 1984 and 1994-2002 indicate important time periods for development of related technology. After 1994-2002, network becomes more mature. The similar peak positions for Between Centrality curve, InDegree Cen-

Figure 4 Patent citation network for thermal-stable polymer nanocomposite between 1936-2000. Up triangle symbols are patents shown in Figure 3.

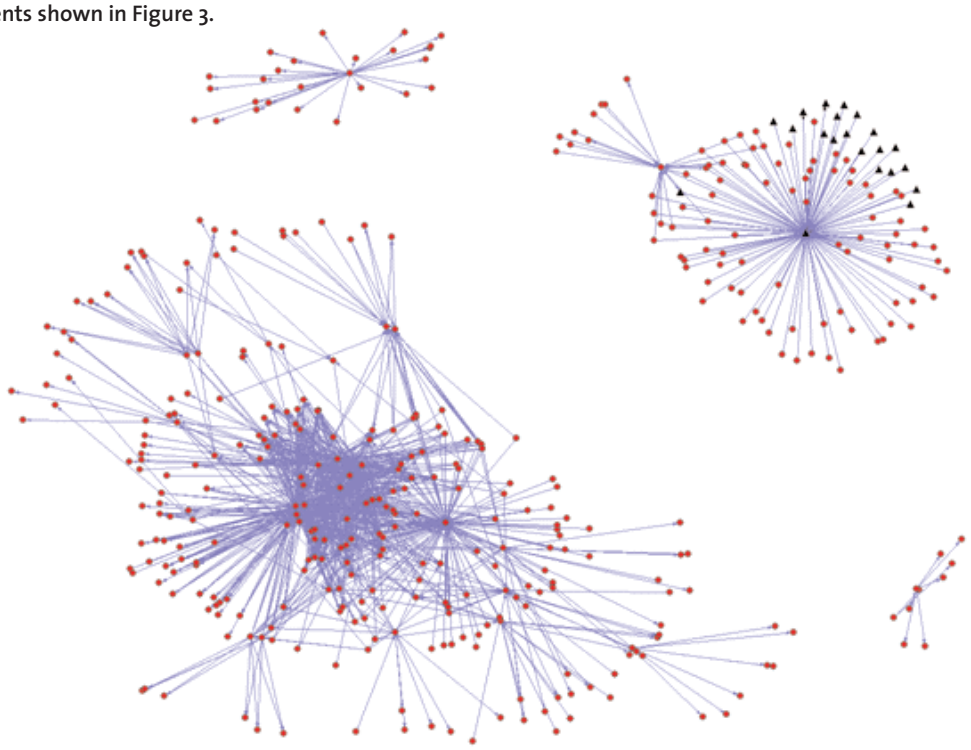


Figure 5 Patent citation network for thermal-stable polymer nanocomposite 1936-2007. Square symbols are patents shown in Figure 4.

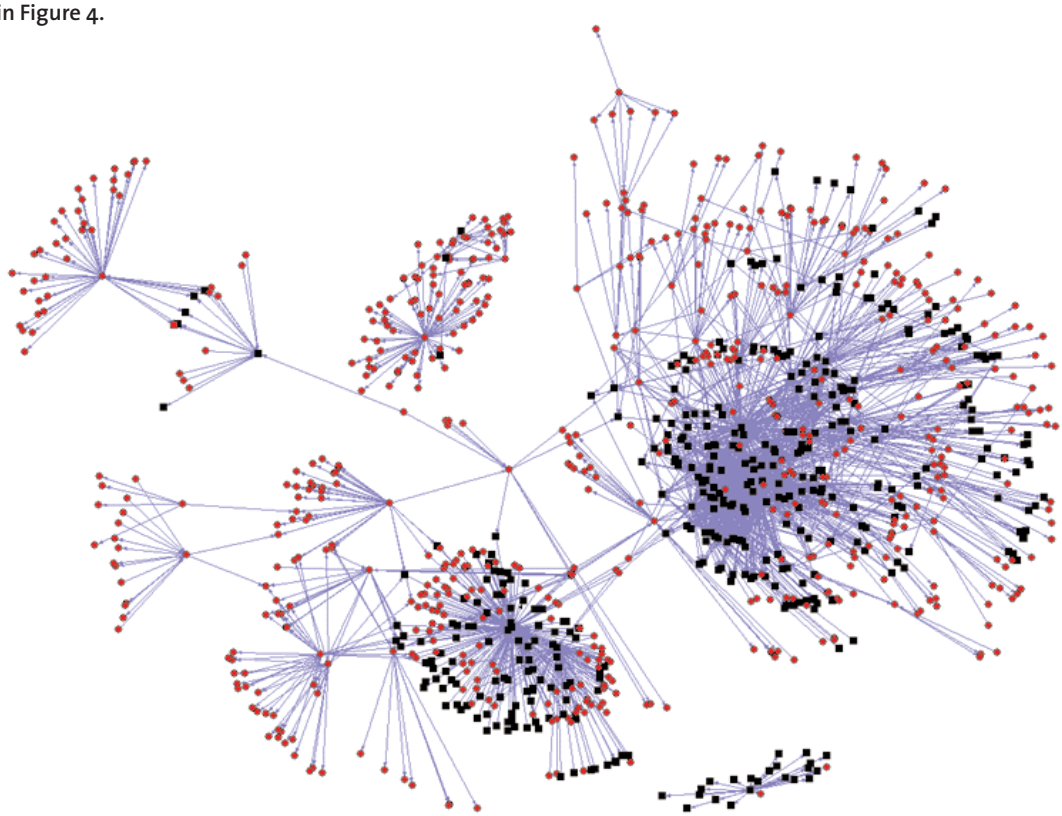
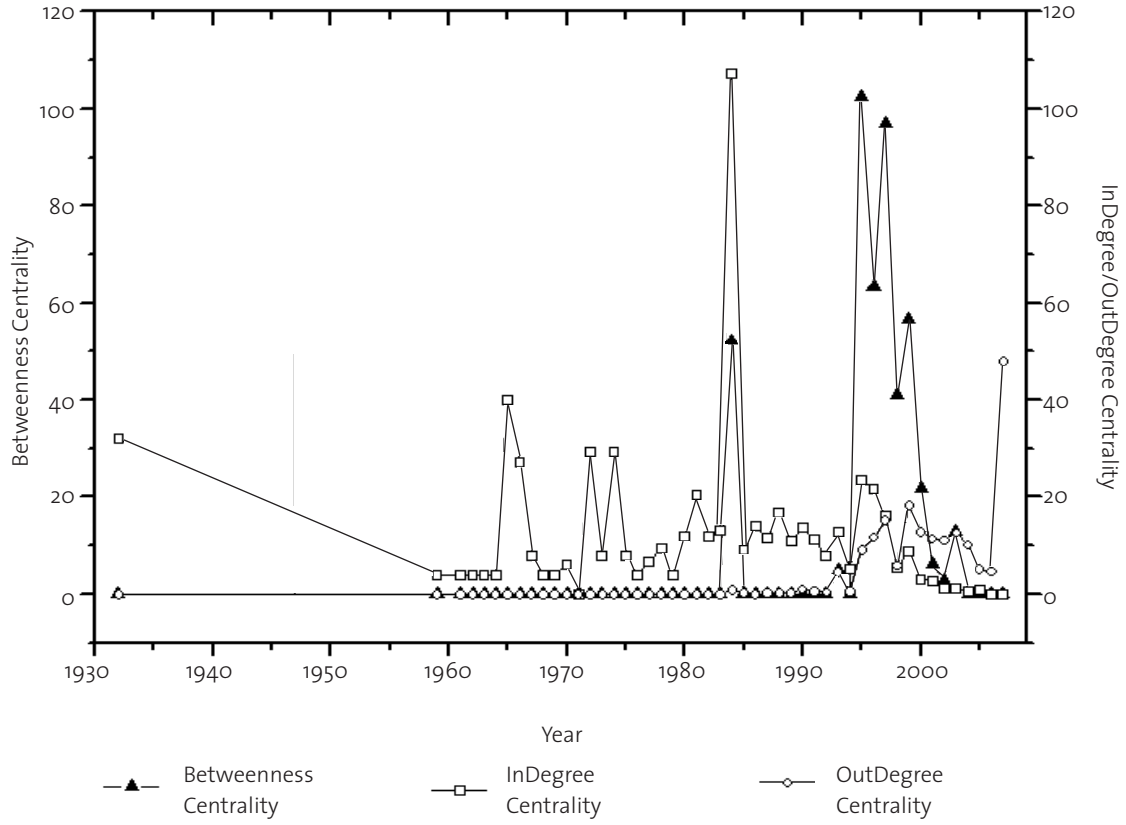


Figure 6. Average of Betweenness Centrality, OutDegree Centraliy and InDegree Centrality for each year.



trality and OudDegree Centrality curves suggest technology diffusion and technology transition are closely associated together.

Network properties (InDegree Centrality, OutDegree Centrality, Betweenness Centrality) for each country are also averaged to determine how significant a country contributes to the development of technology. As shown in Figure 7, the Netherlands, the US, and Switzerland are the three countries with the highest Betweenness Centralities. Hungary, Switzerland and the UK are the three countries with the top InDegree Centralities and the Netherlands, France and Canada are the three countries with the top OutDegree Centralities. However, since each country possesses different number of patents, statistical bias maybe possible for countries with limited number of patents.

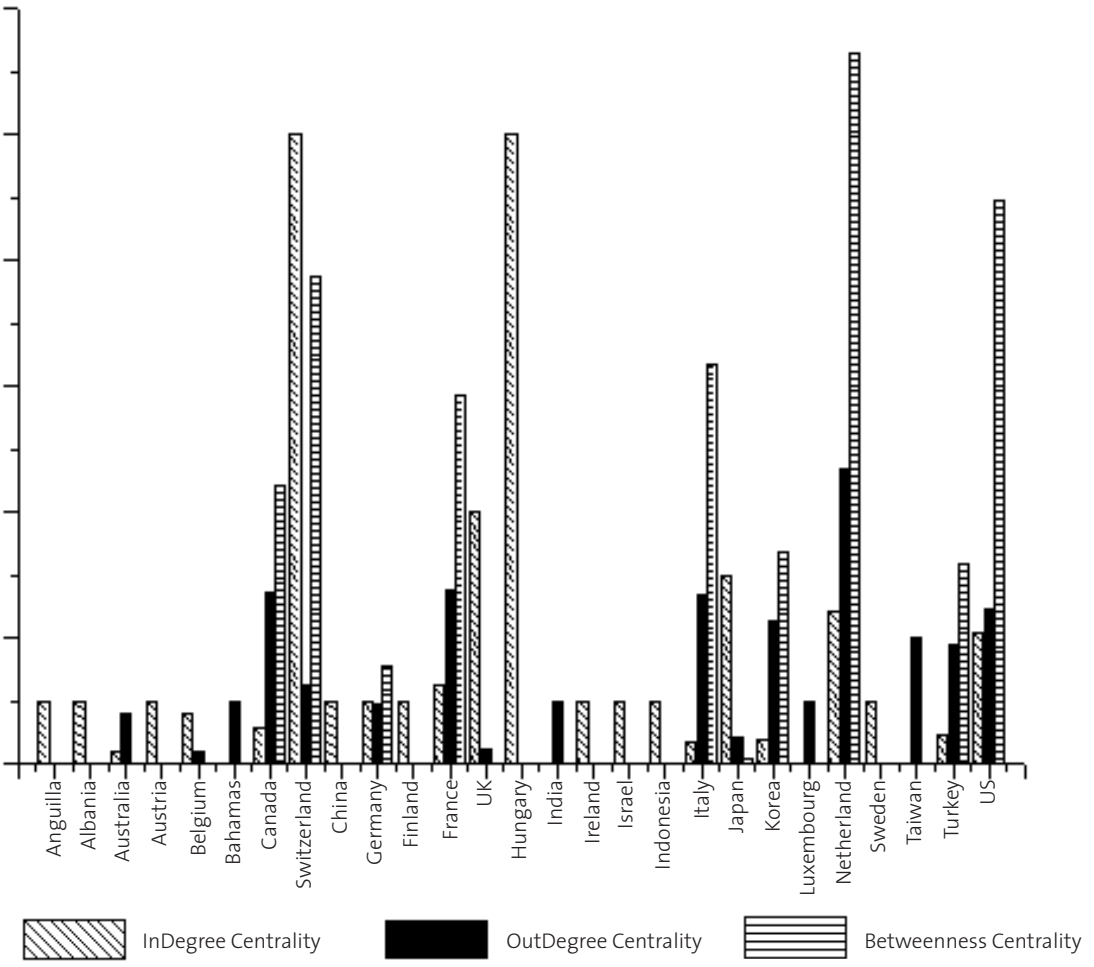
Table 3 shows patents with top 10 network properties. These patents with top network properties are core patents or key technologies that are classifies by aforementioned mentioned momentums of technology development, i.e. technology diffusion, technology convergence, influence, being influenced, technology transition. By examining information of core patents listed in Table 3, intercalated and exfoliated polymer/layered silicate composite material is the most important material in nanocomposite technique development. AMCOL, HYPERION CATALYSIS INTERNATIONAL, SOLVAY ENGINEERED POLYMERS, KABUSHIKI KAISHA TOYOTA CHUO KENKYUSHO UBE INDUSTRIES LTD are top companies in nanocomposite industry.

Quantitative application of patent citation network analysis to business management

The calculated network properties can be provided as a basis for diverse business management applications, where quantitative calculation is required to have mathematical evidence for determining objective business management policies.

1) R&D resource allocation: patent network centrality is a function of time due to the

Figure 7 InDegree Centrality, OutDegree Centrality, Betweenness Centrality for each country.



always-increasing number of patents in the USPTO database. The dynamic network centrality reflects the increase or decrease of importance of a patent over time. The patent holder can estimate how much R&D resource to be introduced to the patented techniques according to the amplitude of the network centrality change of the patent.
2) Performance evaluation: the correlation between how much R&D resource input to generate a patent and the degree of network centrality of the patent can be estimated.

$$Performance = \frac{Network\_centrality\_of\_Patent}{\mathrm{Re}source\_Introduced\_to\_generate\_patent}$$

3) Patent map: a citation network can be converted to a two-dimensional patent map (contour plot) by the use of proper algorithms to allow easy visualization by human eyes and help understand distribution of global patents. This allows quantifying technology development path to obtain optimal patent portfolio and avoid potential infringement.
4) Patent valuation: even though a lot of methodologies have been provided to evaluate patent value, network centrality, which is directly related to degree of importance, might provide a new dimension for patent valuation where quantitative calculation is essential.

Conclusion

Social network analysis on patent citation

Table 3 Patents with top 10 network properties

Ranking	In-Degree Centrality - momentum of technology diffusion	Out-Degree Centrality - momentum of technology convergence	In-Closeness Centrality - momentum of influence	Out-Closeness Centrality - momentum of being influenced	Betweenness Centrality - momentum of technology transition
1	4663230	6632868	4663230	6632868	5552469
2	5552469	6462122	5552469	6462122	5849830
3	5698624	6225394	4889885	6225394	6057396
4	5589152	6228903	4810734	6228903	6228903
5	5760121	5849830	5102948	6861481	5698624
6	5849830	6057396	5385776	7135508	5760121
7	5876812	7217754	4739007	7157516	6462122
8	5877248	5877248	5032547	7160942	6861481
9	5844032	5844032	4894411	7214734	6632868
10	6057396	5698624	5032546	Re40197	5962553

is demonstrated in this study to explore how technology development can be evolved from a citation network which visually represents the essential structure of technology evolution. Also, the linkages between the five different mechanisms of technology evolution and the five network properties, namely the concordance between technology evolution mechanisms and network properties, are defined and proposed in this study in order to provide a quantitative approach toward understanding technology evolution mechanisms for thermal-stable nanocomposite technology. A patented technique plays multiple roles and shows different levels of importance in terms of the proposed five types of mechanism. The evolution mechanism represented by network property is a function of time in the overall technology development. Therefore, by calculating patents' network properties at different points of time, a dynamic and quantitative understanding of technology evolution can be obtained in response to Dosi (1982) and Kuhn (1970).

According to the large number of paints and plastics related patents in Table 2, it can be speculated that the incorporation of nanoparticle into polymer matrix is the major technology to obtain nanocomposite material and conventional painting, resin and plastic industries are easier to be involved in both nanotechnology and composite fields, and thus providing a platform for interdisciplinary convergence.

The similar peak positions for Between Centrality curve and InDegree Centrality curve in Figure 6 suggests technology diffusion and technology transition are closely associated together. Table 3 shows top centrality patents in one type of network property are easily to be top centrality again in other type of network properties. This suggests that each mechanism of technology evolution does not happen alone but is supposed to be more or less associated to other type of mechanisms. In other words, critical patents are easily to be important in all aspects of technology evolution mechanisms.

It is found that 1984 and 1994-2002 are the important years for the development of ther-

mal-stable polymer nanocomposite and exfoliated and intercalated polymer layer silicate are the most critical techniques. The Netherlands, the US, Switzerland, Hungary, France, Canada and Japan are important countries in this field. According to standard industry classification, the largest portion of these patents is related to paints, resin and plastic.

Intercalated and exfoliated polymer/layered silicate composite material is the most important material in nanocomposite technique development. AMCOL, HYPERION CATALYSIS INTERNATIONAL, SOLVAY ENGINEERED POLYMERS, KABUSHIKI KAISHA TOYOTA CHUO KENKYUSHO UBE INDUSTRIES LTD are core companies in nanocomposite industry.

The length of a network tie in figures 3-5 is calculated for better visualization and has nothing to do with any network property. However, the length of a network tie can be proportional to similarity between two patents at both ends of a network tie. So it would be desirable to calculate similarity of two linked patents, for example, by calculating occurrence of the same keyword in the two patents. The obtained similarity can be used as the attribute of network tie. Text mining technique can possibly be applied on patents in each separated sub-domains in Figure 4 to understand the differences among sub-domains. So deeper insight about how technology is evolved in each sub-domain can be understood in future study.

This research proposes a systematic and quantitative method to analyze individual patented techniques as well as obtain an overview of large amount of selected patents. The quantitative method provided in this paper shows a possible way of evaluating patents. And thus, a computerized calculation is possible for potential quantitative applications on business magement, e.g. R&D resource allocation, research performance evaluation, patent map visualization, patent valuation, etc. This provides different ways for patent holders to increase their competitive advantages in their businesses.

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Practitioner's Section

Feasibility of Active Ingredient (AI) development for new biocides in the EU

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Biocides usage covers a vast industrial area and the history of biocide and other antimicrobial agent usage in various forms and applications dates back centuries. While the emerging EU regulations (BPD, REACH and others) strive to increase the safety and the eco-efficiency of chemical products and production processes, such changes may also create voids in the availability of current biocides due to outphasing. The present study evaluated the need for new Active Ingredient (AI) development. The feasibility of such development was explored, and the data of economic feasibility analysis shows that, contrary to general expectations, AI development can become profitable within certain economic boundaries.

Introduction

Biocides (antiseptics, disinfectants and preservatives) are usually broad spectrum chemical agents that inactivate micro-organisms (Russell, 2003; McDonnell and Russell, 1999) and their effects are highly concentration dependent (Russell and McDonnell, 2000). The history of biocide and other antimicrobial agent usage in various forms and applications dates back centuries (Russell, 2002). Micro-organisms, although vital for our health and environment, may also pose a risk to human health and can cause serious problems and economic loss in various industries. Biocides are thus used to disinfect, to eliminate undesired organisms, preserve and conserve various products (Rasmussen et al., 1999). On the other hand, the desired properties of biocides include minimal toxicity and eco-toxicity, yet they need to have spectrum of activity and stability adapted to the application in question (Paulus, 1996).

Biocides are used in a variety of different products and applications, where the consequences of possible microbial contamination and spoilage range from being life-threatening, e.g. in pharmaceuticals (Zani et al., 1997) and in food (Raczek, 2005) to deterioration of product quality and product recall costs with negative implications to consumer choice e.g. cosmetics, skin care products and toiletries (Scholtyssek, 2005). Biocides are also used in the prevention of microbial spoilage of fuel and oilfield operations (Robbins and Levy, 2005; McIlwaine, 2005). Biocides are added to the formulations of polymer dispersions, mineral dispersions and paints (Gillatt, 2005; Schwarzentruber and Gane, 2005; Lindner, 2005). Biocides are also needed for the protection and preservation of plastics, textiles and leather (Dylingowsky and Hamel, 2005; Wypkema, 2005; Hauber, 2005). In the pulp and paper industry biocides play an important role in different processes where they are crucial especially in the prevention and controlling of biofilm formation (Corbel, 2005). An important biocide application is microbiological quality control in cooling water systems and in recreational water applications, such as swimming pools, spas and water amusement parks (Ludensky, 2005; Unhoch and Vore, 2005). In

addition, biocides are used in the protection of industrial wood and water-mixed coolants (Williams, 2005; Siegert, 2005).

Accordingly, the usage of biocides covers a vast industrial area and applications thereof. In 2004 the world biocide demand was 5,300 million dollars from which 2,620 million dollars (49%) was used for preservatives, 1,685 million dollars (32%) for water treatment and 995 million dollars (19%) for disinfectants or for industrial processes. By 2009 the world biocide demand is estimated to grow to 6,880 million dollars (5.4% annual growth from 2004) and by 2014 to 9,050 million dollars (5.6% annual growth from 2009) (Freedonia, 2005). Currently, the biocides industry as a whole is governed by end-industry growth, technological developments, regulatory changes and the growing use of biocides as an aid to improve hygiene (Anon., 2007; Anon., 2008a). On the other hand, the industry and R&D of new biocides faces challenges because of the changing industrial and regulatory environment (Bruns et al., 2005). The registration costs of the EU-wide Biocidal Products Directive including all toxicological tests have been estimated at 3-4 million euros (Bruns et al., 2005), which will not ease the existing stagnation of biocidal product development. Moreover, only limited efforts are being invested in the R&D of new Active Ingredients and many of the companies manufacturing biocides have focused on making new biocide combinations from existing Active Ingredients (AI). The term Active Ingredient (AI) is an even more precise term when referring to the actual compound which is responsible for the functional properties of the biocide. On the other hand, biocidal products may also be formulations of many Active Ingredients (Paulus, 2005; Bruns et al., 2005). In addition, the EU Biocidal Products Directive (BPD) 98/8/EC uses the term Active Substance when addressing Active Ingredients (Anon., 1998).

The BPD 98/8/EC addresses the placing of biocidal products on the EU market. The aim of the Directive is to enforce an authorization procedure based on a risk assessment for products containing biocidal active substance before placing the products on the market. The objective of BPD is also to remove barriers of trade between Member States and create a harmonised high degree of protection for people and the environment (Rasmussen and MacLellan, 2001). The BPD applies to 23 different product types listed in Annex V of the Directive but excludes some product types covered by other Community legislation, e.g. cosmetics (Matthews, 2002; Anon., 1998). The BPD entered into force May 1998 and 24 months was given to Member States to implement the directive. A 10-year period following the implementation deadline within the Member States was given to evaluate all active substances used in all products. After this period, active substances not found from the directive's Annexes I, IA or IB must be withdrawn from the market for use as biocides as must also the products in which they are used (Rasmussen et al., 1999). The EC Commission Regulation of BPD has listed some 1,000 active substances from which only over 300 active substances and product types were included in the original review programme (Anon., 2003). The BPD regulation requires extensive testing of all biocidal products before they are registered for sale and the registration is required for both new and old biocides (Bruns et al., 2005).

Accordingly, emerging EU regulations (BPD, REACH and others) strive to increase the safety and the eco-efficiency of chemical products and production processes. However, it may be argued that such changes will create voids in the availability of current biocides, which may become out-phased. It therefore follows that the chemical industry is in need of new AI development in order to comply with new regulations and demands for increased environmental stewardship. Consequently, we have studied the economic feasibility of new AI development and the need for such development from an industry viewpoint. In order to address these questions, a profitability evaluation for a new AI was performed based on the net present value (NPV) and discounted payback period (DPP). In addition, data was collected by interviews in order to obtain an overview from different industries on needs and views with reference to biocides and new product development thereof.

Methods

Profitability evaluation using a sensitivity analysis

The basic measure of profitability is the net present value (NPV) of a new AI development. A development project should be carried out if the discounted net cash flows during the AI's life cycle exceed the R&D investment, i.e. NPV is greater than zero. Our data is based on general estimates of development costs (Käh-

könen and Nordström, 2009) and as well as on biocide demand (Freedonia 2005) but includes no information on specific competition and manufacturing operations. Therefore, NPV is estimated according to Equation 1.

$$\mathrm{NPV} = \mathrm{I}_0 + \sum_{t=1}^{T} \frac{c \cdot s \cdot D_t}{(1+r)^t} \quad (1)$$

I_0 = R&D investment
T = economic life of the AI to be developed
D_t = demand of biocides in Europe in year T
s = market share of the AI to be developed
c = net cash flow as a percentage of annual sales
r = discount rate

It should be noted that the net cash flow percentage (c) contains implicit assumption concerning operating profit margin, cash cycle of the operations and tax rate. Likewise, the market share depends on future pricing decisions concerning not only the AI but its rivals or substitutes.

Therefore, the purpose of the economic analysis is to explore the boundaries of economic feasibility. The approach is that of a sensitivity analysis or break-even analysis, to be more specific (Brealey and Myers, 2003). In a break-even analysis, the analyst seeks for boundary values that make the projects NPV equal zero. In order to facilitate the comparison of scenarios, we also use discounted payback period (DPP) as an indicator. The discounted payback period points to the minimum economic life (T) that makes NPV positive.

Industry Interviews

Interview data was collected in 2008 and selected Finnish companies were chosen to represent various industries utilizing biocides. The interviewed Finnish companies manufactured 1) adhesives and related products; 2) pharmaceuticals; 3) cosmetics and skin care products; 4) polymer dispersions; and 5) biocides for the use of mainly pulp and paper industry. In addition, four companies operating in the paint industry were also included in the study but the data was collected by using a questionnaire form. The oral interviews were conducted in a semi-structured manner (a focused interview) (Hirsjärvi and Hurme, 1993; Tiittula and Ruusuvuori, 2005). All the interviews were recorded and documented in writing afterwards. Although the interviews dealt with three different themes (Table 1, see appendix 1), only the answers concerning the focus area of the present study were analyzed.

In addition to the interview data collected from the industries utilizing biocides, a representative from the Finnish Allergy and Asthma Federation was interviewed (Table 2, see appendix 2). The interview on preservative allergies was also conducted in a semi structured manner (a focused interview) (Hirsjärvi and Hurme, 1993; Tiittula and Ruusuvuori, 2005) and the interview was recorded and documented in writing afterwards.

Results

Profitability of a new biocide

The basic parameters of the NPV model are R&D investment, demand and discount rate. After setting values for these parameters, we have sought the break-even values for market share and net cash flow percentage. Based on a previous study, the R&D investment is estimated to be € 3.13 million (Table 3).

The demand estimates are only for Europe and are based on the summed value of the demand in Western and Eastern Europe in 2009 (Table 4). According to the data in Table 4 the biocide demand in Europe as a whole in 2009 is 2,060 million dollars. Converted to euros (€ = US$ 1.3705 in 2007; Anon., 2008b) the demand for biocides in 2009 in Europe is 1,503 million euros[1]. The expected growth for the biocide demand of the world is estimated as 5.6% annually from 2009 until 2014. This growth estimate of the world biocide demand is used in the calculations although covering only Europe. The new AI is assumed to be on the market at the beginning of the year 2009 (t=1) and on the market for at least until 2030 (T=22). The estimated market life is in alignment with the long life cycles of the many currently used biocides. As there is no growth estimate beyond 2014 provided by Freedonia (2005) or any other public source, the calculations are based on an assumption of an annual growth percentage of 3.0 from 2015 until 2020 and 1.0 from 2021 to 2030.

The diffusion time of a new product into

1) Using the average exchange rate of 2004, i.e. the year the demand forecast was made, the demand in Europe would be €1,661 million.

the market is not taken into account and therefore the market share is assumed to be gained immediately. The discount rate is assumed to be 10% throughout the life cycle. Discount rate and annual demand in euro represent nominal values.

Since the main purpose is to justify further investigations in AI development, we have searched for modest target levels of market share and net cash flow percentage. If one accepts a discounted payback period of 22 years and net cash flow percentage of 5%, the required market share is 0.36%. A market share of 0.18% would be sufficient if net cash flow percentage were 10%. The form of Equation 1 shows that the relationship between these two variables is linear ceteris paribus. If we assume a discount rate of 15%, the respective figures are (5%, 0.51%) and (10%, 0.26%). If we assume a more moderate market growth, namely a constant growth rate of 2.65%[2], a discount rate of 10% and a net cash flow percentage of 5% would require a market share of 0.39%. Table 5 illustrates another scenario with the initial assumptions. Under more favourable conditions, NPV can be much greater than zero and the discounted payback period less than 10 years. As a conclusion, it can be stated that in order to become profitable in the biocide market in Europe, the minimum targeted market share should be approximately 0.4% for a new AI. This is consistent with a net sales target of 6 million euros for the first year.

Views of the industry and need for new biocides

The interviews of the present study indicated that industry representatives are concerned about the changes in legislation and consequent effects on available biocides. The interviewees operating in the business-to-business field highlighted that warning labels in products were not desired. REACH was thought to affect the availability and warning labelling or to increase the prices of the used raw materials. REACH was also seen as affecting companies via the required pre-registration demands. Only one interviewee estimated that the BPD would increase prices of biocides. This same interviewee also believed that no new AIs would be able to enter the biocide market due to the high costs of BPD for new AIs. In addition, eco-labels were also mentioned as affecting the use of biocides.

Depending on the industry, preservatives such as formaldehyde (and formaldehyde releasing compounds) and parabens were named as controversial biocides. Formaldehyde was avoided or not used at all due to its toxicity, but also due to changed customer demands, the EU Water Framework Directive and due to environmental labels such as the Blue Angel (Der Blaue Engel). Representatives who mentioned these were from the adhesives and related products company and the polymer dispersions company. The industry representatives of the pharmaceuticals and cosmetics field stated that there is a trend to discontinue the use of parabens due to possible allergies and negative media hype. These examples indicate problems with currently used biocides and the lack of alternative biocides.

Properties needed for new biocides

Differing views were presented as to the kinds of properties a new biocide should ideally have. Only one interviewee stated that a new biocide should comply with certain standards so that use of such a biocide would not lead to demands for warning labels. Moreover, the biocide should be effective so that it could be used only in small amounts. On the contrary, however, another interviewee stated that it would be useful if a new biocide could be used in large amounts, but without warning labels. In general, interviewees were of the opinion that a new biocide should be highly effective, broad-spectrum and safe to use with no sensitization problems. In addition, the interviewees from the paint industry all agreed that there is a clear need for new dry film preservatives.

There also appears to be need for biocides that would function with a completely different mechanism compared to the biocides in use currently. Such a new biocide could be e.g. some natural raw material that would have biocidal attributes. It was also mentioned that a new biocide should also be suitable for many different kinds of products and have a good solubility. The company manufacturing biocides listed cost-effectiveness as the most important attribute in addition to the biocide being safe and rapidly degradable to harmless end-products.

A highly important issue that also arose in

2) This growth rate leads to the same demand in 2030 as the original estimate.

Table 3 The estimated start-up costs for the development of a new AI

Start-up costs / AI	Average cost (M€)
R & D	0.240
EHS risk evaluation tests according to regulations and dossier composition	2.650
Registration fee in the EU	0.120
Other e.g. manufacturing costs	0.120
Total costs	3.130

Source: Kähkönen and Nordström, 2009

Table 4 World biocide demand (in millions of dollars) from 1999 to 2014 and percentage annual growth

	Biocide demand (M US$)				Annual Growth %		
Item	1999	2004	2009	2014	04/99	09/04	14/09
World GDP (bil 2000 $)	43,000	51,050	62,150	75,900	3.5	4.0	4.1
$biocide/mil $ GDP	98	104	111	119	--	--	--
World biocide demand	4,225	5,300	6,880	9,050	4.6	5.4	5.6
North America:	1,925	2,300	2,890	3,620	3.6	4.7	4.6
United States	1,735	2,060	2,580	3,220	3.5	4.6	4.5
Canada & Mexico	190	240	310	400	4.8	5.3	5.2
Asia/Pacific:	820	1,145	1,650	2,465	6.9	7.6	8.4
China	138	286	553	1,048	15.7	14.1	13.6
Japan	416	473	544	627	2.6	2.8	2.9
Other Asia/Pacific	266	386	553	790	7.7	7.5	7.4
Other Regions:	290	425	600	840	7.9	7.1	7.0
Latin America	104	127	169	222	4.1	5.9	5.6
Eastern Europe	127	215	320	472	11.1	8.3	8.1
Africa/Mideast	59	83	111	146	7.1	6.0	5.6
Western Europe	1,190	1,430	1,740	2,125	3.7	4.0	4.1

Source: Freedonia, 2005

the interviews was a need for new biocide efficacy testing methods. Interviews of the paint industry indicated that the most important area for basic research on biocides is determination of biocide efficacy. In addition, the representative of the company manufacturing adhesives and related products stated that microbiological knowledge and business related to biocide efficacy and product preservability is still limited. More efficient and specific methods for biocide efficacy testing are thus called for. They are also crucial for the development of new biocides as giving a basis for the development process of a new AI.

In addition, also the non-biocidal solutions and alternatives to chemical biocides were discussed in the interviews. Although there was no direct question on non-biocidal means for microbial control, many of the interviewees mentioned non-biocidal alternatives during the interviews and the importance of phrases such as 'preservative-free' in advertising. The representative from the cosmetics field emphasized that there is an ongoing trend towards reducing the use of preservatives. This interviewee also stated that if the product can be marketed as 'preservative-free', it clearly adds value to the product. The representative from the pharmaceuticals field also mentioned this same trend and the possibility of using e.g. disposable packages or preserving packaging technology instead. This interviewee also mentioned that there is a trend towards disposable packages.

The Finnish Allergy and Asthma Federation interview revealed aspects of the sensitizing potential of many preservatives. The interviewee emphasized that even though the number of some allergies has increased during recent years, this should not be interpreted as a proliferation of allergies in general. Rather, the increase is due to increased knowledge on

and diagnostics of allergies. Even though allergies have not increased, the interviewee mentioned that the so called 'sensitivity markets' have grown during the last few years especially in the cosmetics field. In new AI development the sensitizing aspect is therefore a crucial aspect to be taken into account as many preserved products are used on skin on a daily basis. On the other hand, industrial preserving methods should be environmentally friendly and should not be bio-accumulative.

Limitations of the study

The interviews conducted in this study represent a qualitative research method. A potential challenge in achieving validity in qualitative research is researcher bias, arising out of selective collection and recording of data, or from interpretation based on personal perspectives (Johnson, 1997). This also applies to the present study as the interviewed sample was small and consisted of industry representatives who were not selected through random sampling. However, although the number of interviewees is rather limited, it is to be noted that the interviewees represented companies with a vast range of biocide application needs. Moreover, at this point the aim of our study was only to shed some preliminary insight into the needs and views of the industry and whether there is any indication that such views take into account the cost of new biocide/AI development.

In this study, the calculations were performed in order to give a rough estimate rather than precise figures. This was due to the limited initial information and consequently the many assumptions that had to be made. Moreover, the conversion of the initial numeric data from dollars to euros clearly is dependent on the used exchange rate and therefore affects the value of the turnover and cash flow estimates. The calculations were performed based on the biocide market size estimates published in 2005 as this was the newest available information. However, the current financial situation clearly has an influence and more recent market growth assumptions would presumably be different and more moderate. The financial situation was, however, taken into consideration by making the longer term growth assumptions rather on the low side in order not to overestimate the market size. In addition, the calculations were performed using a sensitivity analysis where various different estimates of the cash flows were calculated.

The calculations of this study focused only on the assessment of the net present value and the discounted payback period based on the basic initial costs which composed mainly of the registration fee, EHS risk evaluation costs and moderate R&D costs. However, developing an AI with the attributes specifically wished for by the industry representatives might increase the estimated R&D costs even heavily. But as the estimation of these specific R&D costs would be highly inaccurate and difficult, the calculations were carried out using a very moderate estimate of the start-up costs. Clearly, these calculations can be made more accurate when more information on the development and other costs is available. In addition, the calculations in this study do not take into account those R&D costs and development processes which do not lead to a desired outcome. In further studies when more initial information is available, different and more complex calculation models can be used for profitability evaluation.

Discussion

While the changing industrial environment of the biocide market and the high registration costs of the BPD are not generally seen as an incentive for developing new AIs, the industry needs should be seen as one instead. The conducted interviews echo the opinions of industries and speak on behalf of new AI development. In addition, the limited number of available biocides can be seen as a problem, especially if the number of the AIs in use currently decreases due to the BPD as has been speculated (Bruns et al., 2005; Chapman, 2003). The EC Commission Regulation of BPD has listed some 1000 active substances from which only over 300 active substances and product types were included in the review programme (Anon., 2003).

The data of the present study does not support the general opinion that development of new AIs would be economically unfeasible. Rather, it is evident that the payback time for new developments will increase, but as the present study has shown, the market shares for profitable operating in the European market are not overwhelming. If one accepts a discounted payback period of 22 years and net cash flow percentage of 5%, the required market share is 0.36%. Therefore, in order to become profitable in the European market, the minimum targeted market share should be

Table 5 Estimated net present values using a discount rate of 10%

			Market share %			Market share %		
			0.3			0.4		
			Cash flow %			Cash flow %		
			5	10	20	5	10	20
Year	Time period	Discount factor	NPV of cash flows (M€)			NPV of cash flows (M€)		
2009*	0	0	-3.13	-3.13	-3.13	-3.13	-3.13	-3.13
2009	1	0.909	-2.93	-2.72	-2.31	-2.86	-2.58	-2.04
2010	2	0.826	-2.73	-2.33	-1.52	-2.59	-2.06	-0.99
2011	3	0.751	-2.54	-1.95	-0.77	-2.34	-1.56	0.02
2012	4	0.683	-2.36	-1.59	-0.04	-2.1	-1.07	0.99
2013	5	0.621	-2.18	-1.24	0.65	-1.87	-0.61	1.92
2014	6	0.564	-2.02	-0.9	1.32	-1.65	-0.16	2.81
2015	7	0.513	-1.86	-0.59	1.95	-1.44	0.26	3.64
2016	8	0.467	-1.71	-0.3	2.53	-1.24	0.65	4.42
2017	9	0.424	-1.58	-0.02	3.08	-1.06	1.01	5.15
2018	10	0.386	-1.45	0.23**	3.60	-0.89	1.35	5.84
2019	11	0.350	-1.33	0.47	4.08	-0.73	1.68	6.48
2020	12	0.319	-1.22	0.7	4.53	-0.58	1.98	7.08
2021	13	0.290	-1.11	0.91	4.94	-0.44	2.25	7.63
2022	14	0.263	-1.02	1.1	5.32	-0.31	2.50	8.14
2023	15	0.239	-0.93	1.27	5.67	-0.2	2.74	8.60
2024	16	0.218	-0.85	1.43	5.99	-0.09	2.95	9.03
2025	17	0.198	-0.78	1.58	6.29	0.01	3.15	9.42
2026	18	0.180	-0.71	1.71	6.56	0.10	3.33	9.78
2027	19	0.164	-0.65	1.84	6.80	0.18	3.49	10.1
2028	20	0.149	-0.59	1.95	7.03	0.26	3.64	10.4
2029	21	0.135	-0.54	2.05	7.24	0.33	3.78	10.7
2030	22	0.123	-0.49	2.15	7.43	0.39	3.91	11.0

* This row represents time at the beginning of the year 2009 and the cash flows in the row represent the start-up costs.

** The year of the discounted payback period, DPP, (i.e. the value of the NPV is positive) is indicated by highlighting the cell with dark gray.

approximately 0.4% which is consistent with a net sales target of 6 million euros for the first year. Under more favourable conditions, NPV can be much greater than zero and the discounted payback period less than 10 years.

A market share of 0.4% can be seen as an achievable one especially as some over 300 AIs are currently included in the review programme of the BPD. Hypothetically, if all 300 AIs would have an equal market share it would equal 0.33%. The market share limit calculated in the present study is somewhat higher but still in the same range. Thus for an efficient, new product, a market share of 0.4% appears realistic. In addition, the demand for new, efficient biocides can be argued to increase as the number of currently used AIs decreases due to implementation of the BPD which reduces the amount of alternative AIs.

In addition to chemical preservatives, there is also interest in alternative preservation methods. However, it seems highly unlikely or even impossible that these would rule out the chemical methods entirely. Rather, the development of non-chemical methods is extremely important, but in many cases these methods can be utilized alongside or in addition to chemicals. As an example, the development of preserving package technologies is a fertile field, whereas increasing the amount of disposable packages vs. chemicals should be carefully evaluated. Disposable packages increase the amount of waste and therefore are not necessarily the only sustainable alter-

native for chemicals.

As the BPD requires registration of both new and old biocides (Bruns et al., 2005) also existing AIs in the market will require investments. Consequently, this would argue on behalf of the importance of new AI development as costs of registration are inevitable if the aim is to stay in the biocide market. In addition, as the biocide market may become more stagnated, a new AI may rapidly gain visibility and the producer of a new AI may become recognized as a technology leader. On the other hand, if new AIs are not developed, then it may be wise for companies to include a broader range of control of biodegradation, including also non-chemical means of control. Controversially, however, the increasing demand for non-chemical, ecologically more acceptable means for control may become a barrier to entrance of new AIs. On the other hand, it is unlikely, that non-chemical alternatives solely would be adequate for all purposes in the near future, whereas a new AI together with non-chemical means could perhaps offer a highly versatile product portfolio for a biocide producer.

Although one of the goals of the emerging regulatory framework for chemicals within the EU strives to boost innovation within the Community, it is evident that the implementation of regulatory initiatives may also pose a possible barrier for new AI development. Evidently, the competitiveness of the EU market is inherently tied also to international trade and harmonisation of regulatory initiatives worldwide. If harmonisation of legislation does not support the competitiveness of the EU as intended by the Community regulatory framework, unexpected challenges for AI development might occur, as global requirements will differ and increase the cost of a "universally" acceptable new AI.

New AI development should be based on a standardized and reliable protocol for biocide efficacy testing. However, at the moment efficacy testing methods for biocides vary according to the industry application and can also be seen as a barrier for new products entering the market. The pharmaceuticals industry is an example of an industry which has a clearly defined testing protocol for efficacy testing and acceptance criteria (Meyer et al., 2007). In many other industries various different efficacy testing methods and protocols exist (Gillatt, 1991; Heinken, 2000). Therefore, biocide efficacy testing is clearly an area that needs to be further studied and developed in order for the efficacy of new AIs to be verifiable.

In conclusion, development of new AIs is technologically and economically feasible. Clearly also non-chemical alternatives for preservation should be considered, possibly in conjunction with chemical biocides development. Alternative means of microbial control are often less toxic to the user, consumer and the environment, but limited as to the range of applications where such methods can be used. On the other hand, chemical biocides clearly suffer from toxicity, which, however, is inherent to their activity and required efficacy profile. Consequently, the challenge for biocides and control of biodeterioration in the future is ingrained into formulating the "non-toxic poison" for which the price-tag remains to be determined.

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Appendix 1

Table 1 Themes and topics of industry interviews

INDUSTRY		
Adhesives and related products, cosmetics and skin care products, polymer dispersions	**Pharmaceuticals**	**Biocides (for the use of mainly pulp and paper industry)**
THEME 1. MICROBIOLOGICAL RISKS		
• what microbes, what kind of problems	• what microbes, what kind of problems	• most important industries as clients what microbes, what kind of problems (that clients have)
• preservability of products	• how much preservatives are used	• most important AIs in manufactured biocides
• quality control, detection of spoilage	• the meaning of use-by date in pharmaceuticals	• prevention of spoilage or prevention of pathogens
• biocides in use currently (in products / processes)	• quality control, detection of spoilage	• alterations in biocide formulae due to microbial resistance
• resistance towards biocides	• biocides in use currently (in products / processes)	
	• allowed concentrations of preservatives	
	• resistance towards biocides	
THEME 2. REGULATION AND RISKS OF CHEMICALS		
• eco-labels, warning labels or environmental strategies affecting biocide use	• changes in use of biocides	• eco-labels, warning labels or environmental strategies affecting biocides
• changes in use of biocides	• regulations or directives affecting the use of preservatives	• changes in formulas of biocidal products
• effects of the BPD *	• requirements of preservatives in sales permit applications	• effects of the BPD
• needs from (new) biocides	• differences between EU and USA with reference to preservatives	• clients' needs from (new) biocides
• interests in cooperation with biocide development	• needs from (new) biocides	• importance of development of new AIs, interests in cooperation with AI development
	• interests in cooperation with biocide development	• non-biocidal alternatives and their relevance
THEME 3. CONSUMERS		
• complaints due to microbial spoilage	• complaints due to microbial spoilage	• could some new chemical operate as sales promotion (for your clients' products)
• could some new chemical operate as sales promotion (for products)	• preservatives with reference to allergy tests	
• sensitivity (human) to preservatives **		

* not asked from the representative of the cosmetics field

** asked only from the representative of the cosmetics field

Appendix 2

Table 2 Allergy and Asthma Federation (Finland) interview

QUESTION THEMES	Specific questions
Preservative allergies	• number of allergies and source of information of allergies
	• preservatives causing most allergies and possible recommendations for companies of which preservatives to use
	• product types mostly related to allergies
	• allergy tests and evaluation methods
	• consumer awareness of preservatives
	• correlation between microbes and allergies
”Allergy safe”	• are there international standards for allergy labels
	• number of applications for the “allergy safe” label and types of products applied for
	• effect of “allergy safe” label on consumer purchase decisions
	• new product groups having the allergy label
	• recommendations for companies on preservatives

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Practitioner´s Section

How to implement 'access to medicine' AND enhance economic performance: business model options for global access

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'Access to medicine' or 'global access' is at the core heart of corporate responsibility for pharmaceutical companies. Corporate responsibility, however, is not restricted to a philanthropic dimension (such as donations), which is often referred to as corporate citizenship. It also includes corporate social responsibility (in the narrower sense) and corporate governance and thereby paves the way for linking corporate citizenship – "to be a good corporate citizen and contribute to the community" – on the one hand and economic performance on the other hand. In the domain 'access to medicine' providing market access to the bottom of the pyramid is an instrument addressing both sides – corporate citizenship ("giving to the public") and corporate responsibility to its (economic) stakeholders ("creating economic value").

A. Introduction – What is corporate responsibility?

Corporate responsibility (CR) is becoming a stronghold on board agendas. While sometimes seen as an instrument for communication (and hence being duty of the public relationship departments), companies are increasingly perceiving it as a valuable management tool: it allows for ensuring sustainability including economic and financial sustainability, managing risk such as reputation at stake and enhancing relationship to stakeholders (rather than just focusing on relationship to investors and rather than just establishing one-way communication to non-investor stakeholders). Therefore, it is more a management function, which "at the end of the year" uses its public relation teams to provide for a consolidated communication effort, the company's sustainability report.

Corporate responsibility basically covers three domains:

- **Corporate governance** primarily focuses on compliance with (inter)nationally established corporate governance codices. This includes, but is not limited to providing for anti-fraud and anti-corruption countermeasures.
- **Corporate citizenship**, 'being a good citizen', is the company's voluntary commitment to non-profit activities. This part covers those activities which are usually perceived under the umbrella of corporate responsibility and corporate social responsibility, respectively, such as giving donations and running non-profit foundations for public research.
- **Corporate social responsibility** (CSR) in its narrower sense addresses the company's responsibility towards the environment (which focuses on reducing the climate

impact of the company's activities), towards its employees (which focuses on establishing appropriate work safety standards and avoiding, e.g., forced labor and child labor) as well as towards its economic stakeholders, its investors.

The roots of corporate (social) responsibility are in the philanthropic domain. Oftentimes, this led to constellations in which the CR/CSR functions of a company were seen as a part of public relations; subsequently the function itself was and is located in PR departments. It, however, can be used as a very powerful instrument for managing reputation risk. Warren Buffet once said that "it takes 30 years to build a company's reputation, but it takes only 30 minutes to destroy it". In the times of fast communication via internet, bad news and bad rumors spread faster than any public relations team can react. Doing something against upfront – reputational risk management – will be cheaper and more reliable.

Analogously, 'access to medicine' also is often perceived as being just an instrument of corporate citizenship. The authors will make a case for the idea that the benefits of 'access to medicine', however, may go well beyond 'just giving'. Under certain circumstances, which are discussed in detail below, there is a valid business case for companies to engage here – going even further and beyond reputational risk management towards tangible economic benefits.

Furthermore, the domains discussed before are the ones which are in the centre of discussions surrounding corporate responsibility. Their nature is a rather defensive one – avoiding non-compliance with regulations and expectations, avoiding the impression of egocentric management, avoiding negative reputation. The authors will make an argument for leaving the defensive, exculpatory approach behind and moving towards proactively shaping an economically beneficial surrounding by using the 'toolbox' usually associated with 'defensive and exculpatory corporate responsibility'.

The rationale for this argument can be made clear by one example. This example rests on the assumption that public health is the foundation for economic activity. Countries which were able to ensure general well-being for all their citizens are likely to be those countries which host stable markets. The authors will discuss below that instable markets may be one of the root causes for the lack of 'access to medicine' – providing the foundation for public health may help stabilizing those markets and thereby opening the door for a successful market penetration. This example may even go further. Beyond ensuring availability of drugs for 'neglected diseases' such an initiative may prevent instability of a company's stable home ground markets as those 'neglected diseases' may very well spread into these home markets and destabilize them.

What is global access?

Before discussing the options for enhancing business models in detail, we want to take a step back and have a look at what global access actually means.

The intensity of public scrutiny against 'Pharma' and 'Big Pharma' in particular is well known. In those respects, which may be addressed by an 'access to medicine' program, there are several aspects and perceptions leading to this scrutiny:

- One major driver is the conflict of being dependent on medical care on the one hand and the enormous profitability of Big Pharma in the past on the other hand. Even in times before the current financial crisis, pharmaceutical companies usually were able to deliver higher shareholder value than most other industries (Angell, 2005).

  The usually high prices for patented brand drugs can be considered as a major driver for this success. On the flipside, however, these prices will exceed the financial capabilities of third world patients up to parts of first world patients. These potential but not-served patients form a large group of "neglected patients".
- The need to continue and outdo the previous year's success as well as analysts' expectations has pharmaceutical companies rely on premium priced drugs. This in turn has companies focus on first world markets. Their economies as a whole as well as the individuals are more likely to be wealthy enough to pay the prices of premium priced drugs.

  In the consequence, other markets are not served – simply due to the fact that they will not be able to pay the bill. These markets are referred to as "neglected markets".
- The aforementioned optimization rule does apply on disease areas, too. If markets, who are not likely / expected to be able to pay the bill, are facing diseases not prevalent

in first world countries, there is a very high likelihood that the pharmaceutical industry in general will disregard the diseases and not spend R&D resources on these disease areas. These comprise the so-called "neglected diseases".

- Although neglected patients and neglected markets may not be served, they may play an important role in the approval process. In order to obtain drug approvals, large clinical studies have to be performed for drugs and their indications.

  It is common among pharmaceuticals to outsource these to offshore service providers in second or third world countries as first world patients are more and more resistant to take part in those trials. The reason for this maybe that they at least have access to other drugs which target the same disease (while being maybe less effective or having more sincere side effects) or the symptoms.

  Public critics point out that patients in offshore countries bear the risk of untested drugs while not being able to get those medicines once they are approved (and highly priced; one example for these critics is Shaa, 2006).

The perception of this behavior led to the triad of 'neglected patients – neglected diseases – neglected markets'. This in turn triggered various initiatives aiming at making medicine available to those, who need it, but cannot afford it: 'access to medicine' or 'global access'.

B. The corporate action plan towards 'access to medicine'

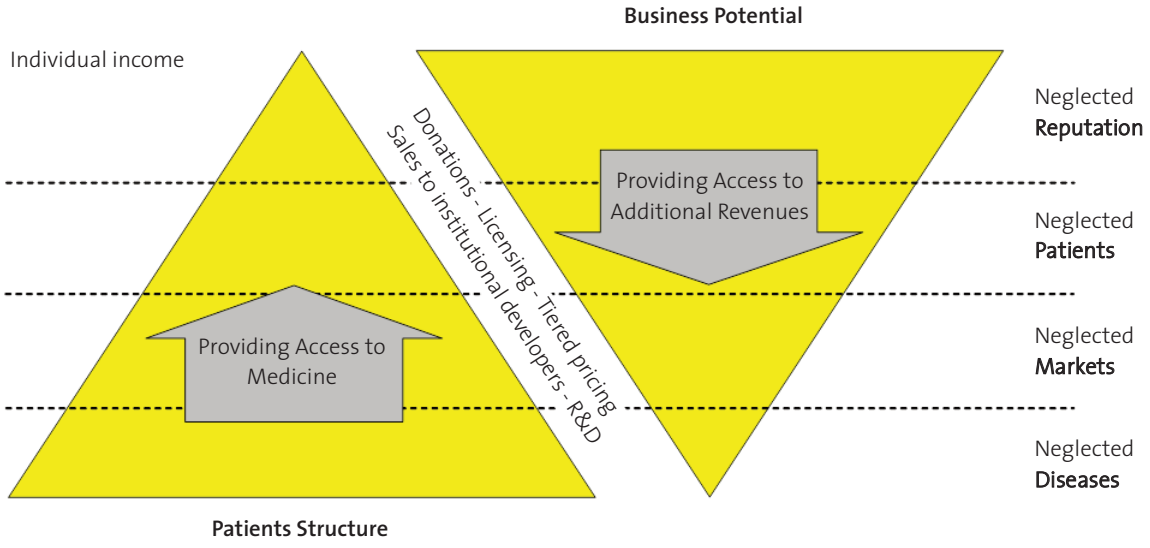
As mentioned before, 'access to medicine' is capable of providing tangibly economic benefits, beyond its philanthropic value and reputation risk mitigation. The underlying principle is the fact that all angles of the triad actually are markets. This connection is often depicted as a pyramid (Prahalad, 2004)(Figure 1).

The pharmaceutical industry is perceived as harvesting the 'top of the pyramid' only, where a small, but wealthy class of patients resides. Neglected reputation once was the initial driver of 'access to medicine' programs and has been well discussed in the past. Working towards the famous 'bottom of the pyramid', however, will allow for unlocking new business potential.

Any response to those opportunities, however, has to be embedded in the corporate strategy. Technically speaking, the first step of each action plan is making global access really a part of the strategy. The triad itself defines the set of potential strategy approaches:

- **'Neglected patients'**: The 'classical' respon-

Figure 1 Unlocking business potential at the bottom of the pyramid



se is providing drugs for free to particular countries. The business case for such a program usually comes from reducing reputational risk, firing the imagination of brands and the firm's responsibility as well as replacing marketing expenses in the narrower sense by marginal cost of production which cannot be recovered. The focus of business case modeling will be on defining the appropriate cost of the products given away for free.

- **'Neglected markets'**: A business case for penetrating additional markets – besides contributing to reputational risk reduction and positive marketing effects – usually aims at providing a tangible economic from shifting economic risk towards partners while again ensuring contribution margin from large volumes and low prices. The main success factor for the business case will not be a matter of quantitative modeling but rather than that finding an appropriate operating model which achieves the aforementioned goals.

  Besides this primary concept, economic stability may further enhance or provide a 'brick' of a neglected markets business model. Serving a market not served before will contribute to public health in the respective country. This may stabilize a market which was avoided before due to perceived or actual instability and hence the initiative may provide the grounds for 'upgrading' such a market to a prioritized emerging market.
- **'Neglected diseases'**: Programs in this group focus on researching and developing drugs that are especially relevant for these markets due to climate related conditions or other reasons, and effectively sold at a low price in those very large markets. Business cases here focus on providing contribution margin for overhead (incl. R&D) by increasing volume. If the volume is large enough, the product of price and volume less the marginal cost of production may provide sufficient contribution margin for recovering the associated R&D cost as well as associated overhead cost for production and administration. The rather intangible benefit of reducing reputational risk as well as the rather tangible benefit of being able to replace marketing cost may be achievable here, too. The key success factor of business case modeling will be defining the set of costs which need to be recovered.

  Beyond this primary approach, there may be a long-term benefit, too. Neglected diseases are not restricted to third world markets far away anymore. Globalization may carry a disease into a first world market; climate change may pave the path for such a disease to advance to first world markets. Having a drug on the shelf in such a case will be a competitive advantage.

Based upon the strategic decision which opportunity to chase, the business case – both in terms of the operating model and in terms of the targeted financials – needs to be translated into an operational plan. Upfront a case will have to be made for each of those options.

In order to make business case modeling successful two requirements have to be fulfilled. At first, the business case needs – despite the intangible effects which significantly contribute to the benefits – to provide a true and fair view in order to truly support decision makers. Secondly, the business case has to be able to gain the support needed and thus has to be able to work out the actual benefits. The strategy approaches stated above and their benefits will be discussed in detail in the following sections giving particular attention on how to ensure successful business case modeling. (It shall be noted that the following analysis of how to establish a business case is focusing on 'hard', tangible economic benefits. The reader should keep in mind that those tangible benefits usually will be accompanied by soft factors, such as positive image / brand effects as well as reduction of reputational risk.)

C. Business enhancement at the bottom of the pyramid - neglected patients

Being aware of their responsibility pharmaceutical companies responded to the challenge in various ways: Merck Co. brought its 'Medical Outreach Program' to life which ensures the availability of vaccines, which originally were developed for first world markets, in third world countries. The total of relief contributions for this program amounts up to 3.3 billion USD according to the company's corporate responsibility report of 2008. The program reaches a number of 104 countries across three continents (Merck & Co. Inc., 2007).

Bristol-Myers Squibb's 'Secure the Future' program goes a step beyond. The program built 'fully fledged' communities for HIV patients

in Africa, where they do not only receive required medication (out of Bristol-Myers Squibb's brand drug portfolio), but are also given a social home.

While it might seem that this kind of program only triggers cost and negatively impacts the bottom line, we argue that there is the benefit of positively impacting the company in terms of reputation risk. The transmission mechanism for translating the intangible benefit of reduced risk into a tangible one was researched and also proven by studies (see, e.g., Bartram, 2001): a company's value is determined by discounting its expected future cash flow; the discount rate will include a risk premium, which can and will be reduced by mitigating the risk drivers upfront which might turn into losses in the future. Hence, in the long run, any risk reduction will positively impact corporate value.

Beyond its origin the approach, however, is not restricted to third world patients. Pfizer, for example, runs a similar program ('Maintain') for U.S. patients in need. Pfizer first set up a patient-assistance program for as early as in 2004 (Pfizer, 2007). In the wake of the financial crisis in 2008/9 Pfizer is extending this program to those who lost their job and subsequently their health insurance due to the financial crisis and thus cannot afford prescription drugs anymore.

It should be noted, however, that Pfizer's program does not cover all prescription drugs (Miley and Thomaselli, 2009). Major oncology drugs, for example, are not included although usually being the ones which are far more expensive. This issue in combination with communicating total cost figures based on list prices once again put those programs under scrutiny. Thus careful design of the business case, which should serve as the platform for the communication strategy, too, is suggested.

Key success factors for successful business case modeling

The first hand benefit of such a program seems to be clear: it is its public relations value. The cost of such a program deserves a more thorough look. Pfizer claims the cost of its preceding program to amount to 4.8 billion USD (Miley and Thomaselli, 2009). This figure is based on the list price of the drugs. This approach, however, may be misleading: The benefit of such a program can, but should not be compared to the revenue usually associated with the products which are now given away for free, as opportunity costs do not arise. Production given away for free is not crowding out production which would be associated with revenue. Rather than that production associated with revenue does simply cease as the market itself has vanished. Thus revenue at list prices will not occur anyway.

We make an argument for considering marginal cost of production instead. (For the sake of completeness, it should be noted that the argumentation stated above must not conclude that no cost occur as there are no opportunity cost. The actual cost of production does occur.) These are defined as the change in total cost that arises when the quantity produced changes by one unit. This approach, however, has to answer the question, why the business case should leave the principles of multi-period product life cycle costing and neglect major cost items – research & development and marketing.

- **The role of R&D:** Any business case for such a program must be distinguished from a business case for a product or target disease area. Drugs given away for free should not be charged with the cost for R&D, as these customers would never be able to purchase the product and hence would never be able to contribute to R&D. Hence, considering R&D cost amortization as part of the business case will be misleading. Putting it the other way round, this principles claims that R&D expenses have to be paid out of "regular actual revenue".
- **The case of marketing expenses:** They usually comprise a major part of a pharmaceutical company's expenses (Consumer Project on Technology, 1999). They must not be allocated to the business cost case for such kind of programs, as the recipients - in Pfizer's program – must have been prescribed those drugs prior to entry in the program. In this constellation marketing is not necessary by definition as the marketing effort relating to this single transaction has taken place before. Thus marketing expenses are not related to the program's benefit at all and hence should be excluded from the analysis.

Considering the aforementioned communications aspects, these paradigms should be considered upfront and also should be part of the associated marketing campaign. Critics will point out pretty soon that the opportunity cost (based on list prices or let alone on an

excessive cost base) allocated to the program are fictional, in particular due to the "lack of market" argument.

Other benefits might be considered on the income part of the business case:

- **Production volume:** The additional turnover resulting from products given away for free may increase overall turnover and hence reduce the fixed cost portion of the cost of goods sold.
- **Revenue from cost reduction:** The overall benefit will come from 'paying' contribution margins to the production facilities out of a de facto PR cost reduction.
- **Reduction of tax burden:** The additional production which is associated with cost but not associated with revenue may decrease overall taxable profit. This in turn will reduce the tax burden. In addition to this, companies may be – depending on the respective tax regimen – able to claim further tax reductions for donations based on the value of their products given away for free (which, of course, has to be properly valued in line with the considerations above).

Considering both tangible and intangible elements a positive business case for any such program is not out of reach.

D. Business enhancement through new distribution channels – neglected markets

The second strategy approach mentioned before aims at serving neglected markets with existing products. Let us consider the following company:

- The drug to address a focal disease of a neglected market is readily available.
- The drug could be provided at an affordable price (see constellation in the previous section).

Despite having products ready our company may still be scared off from some country markets by various reasons:

- The political environment may not be stable enough to justify building a production facility there, while utilizing a local licensee would put the intellectual property at severe risk.
- The delivery requires a highly efficient supply chain in order to make the price affordable; due to the political risk mentioned before, the efficiency cannot be achieved due to required security measures.
- Distribution channels may not be safe. This creates a heightened risk of feeding the grey market in the first world rather than serving the targeted patients.

As stated in an earlier section, the main success factor for the business case for a solution here will not be a matter of quantitative modeling but rather than that finding an appropriate operating model which tackles the aforementioned problems. Economically speaking, the operating model must allow for eliminating the risk or shifting risk towards partners while again ensuring contribution margin from large volumes and low prices.

Thus the established and well understood distribution models for pharmaceutical companies are up for discussion themselves. 'Thinking out of the box', collaboration with new partners – new in the meaning that they are not only new to the company, but new to the industry in general – will be the key:

- This might go as far as using the distribution channels of first world consumer product companies, e.g. the well-known soft drink manufacturers, for the distribution of products. The rationale here is that they need to tackle security issues as well.
- Establishing new distribution models even might involve Big Pharma's natural enemies – those non-government / not-for-profit organizations who point to the dark spots on the industry's clean records and engage in the 'access to medicine' discussions. These organizations know the markets and the issues and therefore may be utilized as monitoring agency in the process.

This theorem can be extended further: the key success factor for any new distribution channels will be - for the moment - the role of NGOs in general. Establishing a new distribution model in order to serve neglected markets is more likely to be successful when supported by a concerted effort by pharmaceutical companies, distributor companies, national governments as well as agencies and others. Experience indicates that there is a high risk of power games between these players. The NGOs – if not considered as actually being involved, e.g. as a monitoring agency, in the actual distribution process – may still be the missing piece here. They may serve as the neutral intermediary between the diverging entities as their primary focus – per definition – is not profit. Hence, a case can be made

for collaborating with those NGOs in an orchestrated way to become active players in the process for effective and efficient access to health.

Key success factors for successful business case modeling

As mentioned above, establishing a business case here will need to combine different elements, partially from the previous sections:

- The business case itself will have to put significant weight on a thorough risk assessment.
- A pricing model should be / can be defined, which provides for positive contribution margins.
- The distribution model actually has to be a 'new one'. It may include and combine the whole array of instruments here: donations, licensing, tiered pricing, sales to institutional developers, etc.
- Any such new distribution model will involve external partners.

Following the concepts described above (considering marginal cost of production rather than total cost, focusing on contribution margin accounting and appropriate consideration of soft factors, including reputational risk) business cases here still will provide significant upside potential.

Similar to the (more obvious) case of neglected diseases discussed below, a long-term benefit of this strategy may arise besides this short-term 'hard fact benefit'. There is a (although possibly weak) reciprocal link between serving neglected markets and the status as a neglected market. The basic assumption of this theory is that serving a market which is neglected and not served yet because of its instability will contribute to public health and to general well being of the respective public in the respective country. This in turn may contribute to stabilizing a formerly instable market. Thus a neglected market may turn into a desirable target market giving further rise to the validity of the business case.

E. Business enhancement through product structure – neglected diseases

A major example for a successful program in the 'neglected diseases' domain is Novartis fight against Malaria. Novartis enforced its Malaria research, although Malaria is not prevalent in Novartis' primary markets. The cornerstone of this program is providing drugs at a very low price to very large market.

One goal behind this initiative is clearly corporate responsibility, as Novartis is highly aware of the death toll Malaria is still causing outside the first world. The program, however, is a good example for an approach which goes beyond purely serving a corporate citizenship purpose – such efforts may not necessarily be solely investments without return. 'Neglected diseases' can very well be profitable disease targets for companies, as the required low price may be offset by the enormous number of patients.

The experience of GlaxoSmithKline proved the validity of this approach (Financial Times, 2009). According to GSK, price cuts of 30-50% had volumes increase by 15-40%; the price reduction of one particular drug yielded a sales increase by 700%.

Key success factors for successful business case modeling

The key lever for a business case for such a program is going away from a total cost of product point of view towards a contribution margin oriented approach. The principle of contribution margin accounting is computing what a product's revenue less the cost directly incurred by producing the product (usually variable costs) contributes to covering the fixed cost of operations and administration. The case of negative contribution margin shows that the product does not even cover its direct (variable) cost neither does it contribute to covering the fixed cost of the company.

In practice, this principle is applied by defining different 'layers' of a company to which costs can be directly allocated. Direct cost of production can be allocated to a single product instance, so that a 'contribution margin I' (CM I) is computed for the product. Overhead cost of production and sales may be directly allocated (without using allocation keys) to a division level, so that a 'contribution margin II' (CM II) is computed for a division by putting the margins of each product of the division against the related overhead and so on.

Applying this principle here aims at creating a positive contribution margin for a particular product by achieving a volume large enough so that the (mathematical) product of price and volume provides at least a positive contribution margin and – in the best case – a margin which substantially contributes to the division's cost. If such a situation is achie-

ved, the bottom line impact is positive by definition.

The pricing decision itself again must not be based on the total cost of the product. The aspects of using total cost are 'covered' by using the contribution margin accounting approach instead.

Besides this short-term 'hard fact benefit' a long-term benefit of this strategy may arise, too. Developing a drug for a third world market does not necessarily mean that the drug will not be used in first world markets. As global epidemics in the past (e.g. SARS) have shown, diseases may spread into first world markets. Having drugs ready in the cupboard certainly will 'help'. The scenario may be considered as far fetched thought. Globalization, however, is just one driver for such developments. Climate change is a fact and will also give rise to diseases from warmer climate zones in places where they are not expected now.

These ideas might be given consideration in the business case at product level, although the impact will be of qualitative nature only – it will be nearly impossible to reliably define a hard quantitative impact for such a case.

F. Conclusion

Due to its importance and its impact on personal level 'access to medicine' / 'global access' deserves maximum attention by the pharmaceuticals industry and also needs to consider new approaches, which to some extent have to be created 'out of the box'. 'Access to medicine' is oftentimes seen as a topic which is part of corporate responsibility and belongs to corporate citizenship in the model depicted above. Nevertheless, it helps the case to create ways which allow for serving the initial purpose – providing access for those who otherwise would get no medication – whilst providing economic benefit at the same time. This will require new coalitions in an orchestrated approach, but also creativity in terms of upfront business modeling.

Besides this result, the concepts discussed above may lead to an additional conclusion. The different types of response to the 'access to medicine' challenge are a result of corporate responsibility in the first place, but also fitting and shaping economic needs. Thus, the authors make – independent of the industry a company is competing in – a case for considering corporate responsibility as a major management tool to be used when a company is facing adversity.

This theory is supported by evidence from the current financial and economic crisis: on the one hand the lack of responsibility of the financial industry towards non-shareholding stakeholders was a major driver of the crisis. On the other hand, using the toolbox, which is provided by corporate responsibility, companies avoid getting even deeper into troubles (e.g. by financially supporting suppliers in major financial woes as seen in the automotive industries) or getting out of the current situation (e.g. by entering low-profit markets or markets which just allow for recovering the costs and thereby ensuring the required utilization of production facilities).

Generally speaking, the corporate responsibility toolbox is a valuable instrument for shaping the corporate future aligned with its strategy. This is true for the strategy options discussed above, for which corporate responsibility can be transformed into a valid business case. In particular the theory holds true for the concept of stabilizing markets through general health improvement by serving neglected markets. Any value-based performance management instrument, such as economic value added (EVA), is incorporating risk into its formula. Thus stability as the counterpart to risk is driving economic success. It is, however, not limited to creating stability in neglected markets – addressing neglected diseases may in the long term ensure stability in first world markets as they need to be prepared for new diseases. Globalization and climate change may pave the diseases' path into the first world. Contributing to have one's home market be prepared may be one piece of the EVA puzzle.

Pharma's corporate responsibility toolbox in the 'access to medicine' domain can provide for another contribution to shaping the future. Entering areas not served before also helps understanding a new area and open the door to a new field for innovation. Biology, for example, was 'neglected' by Big Pharma in the past – nowadays the biotech revolution can be considered one of the drivers of the health care industry. Understanding areas not understood before hence will be a driver for innovation in the future. This shall not comprise a case for patenting natural medicine and natural healing methods, but for serving neglected areas – patients, markets and diseases – and learning from this experience to shape your own future.

These are examples for the power of corporate responsibility. For this reason the authors

expect that the current crisis will strengthen the need for corporate responsibility across industries, as value generation from corporate responsibility will be more visible and more appreciated these days than any time before.

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