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Prospective positioning of industrial players: the case of theranostics

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How are the perceptions of industrial agents affected by newly emerging technological fields? One way to investigate this is to explore the prospective roles that companies involved attribute to themselves and to others by using positioning theory as the point of departure. An appropriate example of an emerging technology to study is theranostics (dedicated diagnostics linked with therapy) given that this affects multiple, relatively unrelated, industries (old and new) simultaneously. By studying annual reports we gain insight into how industries react strategically towards emerging technological fields. We also make a contribution to positioning theory itself.

Keywords: positioning theory; emerging technologies; pharmacogenomics; innovations

1. Introduction

Emerging technologies can be characterised by a high level of uncertainty, e.g. on the technology specifics, and industry structures and networks. At the same time there are virtually only expectations and visions present. In times of such a high degree of uncertainty, industries may need to reorganise themselves and this puts a large amount of pressure on the companies involved. Circumstances such as these often give rise to new competitors (Utterback 1994) and the formation of new connections and ties for those who adopt the new technology (Pfeffer and Salancik 1978). Both ‘old’ and ‘new’ companies in the emerging field have to find a position in the reshuffled industry structure. Positioning as such is well-known in marketing, strategy and business economics literature (Hooley and Saunders 1993; Lefebvre and Lefebvre 1993). This literature addresses prospective positioning into current strategies and activities, which are especially forceful in situations of emergence. Knowing how other companies might react to specific situations is a difficult, yet important and strategically valuable matter. We propose a different angle on positioning in order to gain a better understanding of these reactions and envisage positions as roles that emerge out of discourse. In addition, these roles co-evolve along with the technological developments. What roles do companies attribute to themselves and how do they see the roles of others? Answering these questions sheds more light on how emerging technologies are taken up from a company perspective.

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This paper takes a look at one particular example of an emerging technology that centres on the combination of diagnostics and therapeutics: 'theranostics'. The advent of more stratified patient populations by using genetic information, often described as 'pharmacogenomics', calls for this combination. In other words, it is only possible to prescribe therapeutics that are safe and efficacious for a certain group of individuals with similar gene expressions if a diagnostic tool can be used to demarcate this group. Here, the tension between uncertain prospects and the related reactions of companies also become visible. Both newcomers and established industries are pressured by the 'theranostic storyline' (as we will call it), and several industries will be affected by a newly emerging demand. Following this line of thought, our research question then becomes: do newly emerging storylines, such as theranostics, affect the perspectives of companies (industrial actors) about the industry structure? If so, how are they affected exactly, and are we able to identify shared perceptions within a single type of actor? To answer these questions we believe it is necessary to unravel the prospective roles and strategies present in this field. To do this, we propose a systematic approach based on positioning theory.

Since positioning theory is concerned with how actors position themselves in relation to others, it is a suitable approach to take for studying roles (Harré and Van Langenhove 1994; Van Lente 2003). A specific scene, in this case the theranostics storyline, is seen as the background against which actors actually do this. Actors can position themselves or others. We use positioning theory as a viewpoint expedient to assess roles in emerging structures. Positioning theory, having its roots in social psychology and sociology, is not usually applied to companies as actors. Nevertheless, this approach does resemble other theories coming from innovation studies that take cognitive elements into account. Examples in this respect include Dosi's technological paradigms and trajectories, and Garud and Rappa's socio-cognitive models. Therefore, we will explore whether this extension or new application of positioning theory is possible, and how it relates to other relevant approaches taken in innovation studies. The methodology is concerned with investigating the triad of speech-acts, position and storyline, which is a common representation of positioning theory. A database was created consisting of statements from the 2004 annual reports of companies possibly affected. Analysis of the database then reveals the positions (the sum of speech-acts of all other actors) of groups of actors (e.g. pharmaceutical companies). Whether the position is convergent or divergent and whether there is agreement in self-positioning and the positioning of others will also be assessed. This analysis gives insight into the industry perception of the actors and strategic reaction to the storyline of theranostics.

The next section will outline the theoretical background on emerging technologies and positioning theory. Section 3 elaborates on the methodology used to put positioning theory into practice, for example by explaining how speech-acts are extracted from the annual reports. Section 4 focuses on the results of the theranostics case, while Section 5 concludes this paper by drafting the main insights, points for discussion and recommendations.

2. Theory: emergence and positioning

We are just beginning to understand emerging technologies and their characteristics. High uncertainty of what the technology will bring, who will become involved and in what way, is one of the major characteristics of emerging technologies. In other words, the techno-economic path is diffuse. Furthermore, there is no transparent structure in the broad sense, implying that assessing which actor is linked to what (emerging networks), and for what reason, is non-trivial. Actors hardly know each other, and more importantly they are unaware of the other's interests and standpoints. Also, knowledge structures are unclear: who has which knowledge and who is working on

what technology or device? These characteristics lead to the fact that actors act and interact on the basis of prospects, i.e. expectations and visions. These prospects are reinforced because that is all there is to build on, i.e. there are no or only a few examples of technological artefacts that actually exist. There is also no or very little convergence on solutions (prime technologies) and lots of experimentation is taking place. This all adds up to the diverging state in which emerging technological fields find themselves (Van Merkerk and Robinson 2006). Technological possibilities, number of actors, heterogeneity of actors; all increase and deviate.

Nevertheless, in this seemingly chaotic situation, searching for patterns is useful and still possible. Lessons can be learnt and signals can be found that indicate where the technological field might be heading (Van Merkerk and Van Lente 2005; Van Merkerk and Robinson 2006). Methods of analysis of future technology, such as scientometrics, focus groups, scenarios and technology assessment, are available to help uncover these patterns (Porter et al. 2004). Here, however, we are more interested in how industries react on the emergent storyline, and in this way the use of positioning theory might be constructive.

Positioning theory, being a dynamic version of role theory, is a valuable approach to investigate how stakeholders link their strategies up with (or against) storylines (Harré and Van Langenhove 1994; Van Lente 2003). The basic structure of positioning theory consists of the triadic relations between storyline, speech-act (Searle 1969) and position. Howie and Peters (1996, 51) elaborate on this by claiming that ‘people are viewed as the location for social acts, and the social realm is viewed as involving three processes: conversation . . . , institutional practices and the uses of societal practices’. This is illustrated in Figure 1 (Harré and Van Langenhove 1999).

Having its roots in social psychology, positioning theory has typically been applied to situations in which individuals, in their specific roles or stereotypes, interact with other people. As we mentioned in the introductory section, it is our wish to broaden the scope of this theory by applying it to industrial actors: companies. We will discuss our approach in the following. In exploring this broader use of positioning theory, we draw on the work of other innovation scholars to build up a method that enables us to perform this exploratory work. Subsequently, the concluding section of this paper will discuss whether this broader use of positioning theory is indeed an interesting approach to enrich methods of innovation studies and literature.

We first wish to call attention to three suggestions made by Van Lente (1993) on positioning theory: (1) positioning does not only takes place via conversation and immediate interaction, but also through texts; (2) positioning can be located in the future; and (3) through positioning not only human actors are located, but also non-human technical artefacts. We will not focus on the latter because that would distract us from answering the research questions by adding too much detail

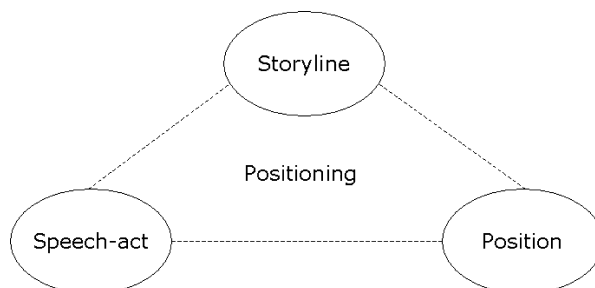


Figure 1. Triadic relationships between storyline, position and speech-act that determine the positioning of an actor.

to the analysis. The first two suggestions will shed ample light on the uncertainties surrounding role attribution and the shaping of technology in emerging technological fields in the future.

We see the grand promises and expectations of the 'diagnostic and therapeutic tandem' as the storyline against which actors position themselves. It is also noted that while storylines evolve over time, this factor should not devalue their imminence for the current situation of the actors involved. This storyline is seen as a somewhat abstract and holistic frame that gives us an idea of how a technology's future might look. Actors that play a part in this storyline, in this case companies, do this by speech-acts on websites, annual reports and through other media. Striking examples include short summaries of their mission statements on the opening page of their websites.

It is important to note that speech-acts are statements that do something ('when you say something, you do it'). Mission statements can be seen as speech-acts in this context, because it may be assumed that companies adhere to them. Speech-acts in the context of a storyline influence the positioning of an actor. Harré and Van Langenhove discerned several distinctions that can be made on the concept of positioning, for example, first-order vs second-order, performative vs accountive and self vs other positioning (Harré and Van Langenhove 1999). The latter is the most revealing: it concerns speech-acts about how actors see themselves and others in the light of emerging technologies.

In the triad presented above a large part is played by the storyline as something that sets the scene for positions and speech-acts. When placing this in the light of other innovation studies, similarities can be found with, for example, technological paradigms and trajectories. Dosi (1982, 148) translated Kuhn's notion of a scientific paradigm into a technology analogy and defined it as: 'an outlook, a set of procedures, a definition of the relevant problems, and of the specific knowledge related to their solution'. Within such a paradigm a direction of advance is programmed, which Dosi refers to as a 'technological trajectory'. The connection with evolutionary economic studies of technical change and innovation (Nelson and Winter 1977; Nelson and Winter 1982) becomes clear when he defines two 'selection layers': the first one establishes the direction of mutation or technological trajectory, while the second one concerns selecting along the lines of this trajectory. In the same vein, Garud and Rappa (1994) present a socio-cognitive model to explain technology evolution and path creation. It revolves around three elements that mutually influence each other: technological artefacts created by researchers, the beliefs they have about them and the routines or belief systems they have for evaluating whether the artefacts meet their expectations. The interactions between artefacts, beliefs and belief systems show a large degree of similarity with technological paradigms. In analogy with these technological paradigms and belief systems, we treat the storyline in this paper as a cognitive construct that sets the scene for the actors involved. Therefore, we focus on the dynamics 'within' such a storyline and not on the dynamics of the origination of such a construct. By taking this approach we hope to create a bridge between cognitive framing through storylines, which take the form of expectations and visions, and how actors react to them.¹ It should be stressed at this point that storylines and the related visions and expectations concern a prospective situation, while paradigms and belief systems shift more to present situations.

In the light of positioning theory, we chose to focus on self and other positioning, because in strategic games people articulate who they are and how they perceive others. By systematically looking at what companies say about themselves and others, in relation to the theranostics storyline, positions can be revealed. The way in which actors give each other congruent roles tells something about the actors' perspectives on the state of a field. Given that we term this as an emerging field, convergence in terms of positioning is expected to be very limited.

While positioning theory is the anchor point that inspires us to answer the research questions, in order for us to broaden the scope to industrial actors two adaptations have to be made. First, the discourse we analyse is more an abstracted than a social discourse. This means that, because of the annual reports that we used as a source of speech-acts, the degree of diversity of speech-acts is limited and there is an inability to include direct reactions on each other's speech-acts (there is no conversation).

Second, the notion of strategy is introduced, because strategies are the entities in which companies articulate prospective speech-acts. While companies position themselves towards others and towards the storyline in general, they can still refer to different strategies. Strategies describe how companies deal with a new technology and in particular how to deal with the research and development on that technology, and in the context of other actors, the way in which collaboration or non-collaboration can enhance their innovation processes. Because theranostics deals with two different pools of technology it is important to know how the connection between diagnostics and therapeutics is formed, and analogically how diagnostics companies and therapeutic companies position themselves towards each other. In the research and development pipeline of these companies the sequence of events will become of crucial importance when executing a certain positioning strategy. For example, if a pharmaceutical company wishes to develop a diagnostic test in parallel with a pharmaceutical product and it seeks to engage a diagnostic company to assist, they will need to set up their development process in such a way that it connects well with the innovation process of the diagnostic firm. Because this approach places great emphasis on the sequence of events, the concept of 'script' might be helpful.

We use the notion of script in identifying the different strategies that the relevant companies can adopt.² Nootboom (2000) sees a script as the (standardised) order or sequence of events that are followed when participating in an act. The most prominent example is the differences in scripts of going to a regular restaurant as opposed to a fast-food restaurant. The order of certain events, e.g. paying, is reversed and altered by the introduction of another concept (script). There are then three ways in which innovations can influence a script: (1) events themselves can change; (2) events can be replaced by another event or be removed; and/or (3) the order of events can change. De Laat makes a valuable contribution by showing that scripts can be prospective, for which he introduces the term 'fictive script' (De Laat 1996), which is in line with Van Lente's notion that positioning can take place in the future (Van Lente 1993). The scripts that describe what companies need to do to obtain approval for a drug or diagnostic are to a certain extent fixed. In the case of pharmaceutical companies an example includes the drug development pipeline. Companies are positioning themselves and others in relation to these fixed steps. The three distinguished development approaches can be translated directly in these scripts: (1) the therapeutic script precedes the diagnostic script; (2) vice versa, and (3) a mixture of both scripts where the outcome in practical and regulatory terms is the most uncertain. In Section 4, which focuses on the case study, these three scripts are explained in greater depth.

3. Method

According to positioning theory, roles or positioning cannot be seen as fixed attributes but as a dynamic outcome of the triad 'speech-act', 'position' and 'storyline'. Also, positioning theory teaches us that self-positioning needs to be supplemented by the positioning of others. If an individual sees himself as an authority on a particular scientific subject and others fail to acknowledge that, then that individual's position as an authoritative scientist will not have much value and his subsequent speech-acts will not have the desired effect.

The speech-acts of companies were systematically charted by abstracting them from their 2004 annual reports. Subsequently, these speech-acts were incorporated in a database of positioning statements that allowed us to compare how actors position each other. We focused on annual reports because they are platforms for companies to make claims about what they intend to do in the future. Moreover, these claims are not only rhetorical; they also have the pretension to be followed given that in their annual reports companies need to account for their actions towards their stakeholders. Because of this, the claims made in these reports are also constructed under close scrutiny and subject to rewrites.³ In this way, the stakeholders will control the strategic claims made by those companies and keep false claims to a minimum. At the same time, the decision to focus only on companies listed on the stock market also had a more practical reason: it made it easier to demarcate the research. As another down-sizing criterion we only focused on annual reports from 2004 to construct a sample which was as complete and well-defined as possible, because at the time of collecting the data this was the most up-to-date information available.⁴

The sample was compiled by combining several lists of companies that play a role in the pharmaceutical, life sciences and diagnostics industry. These lists originated from websites on life sciences,⁵ articles or books dealing with this industry (Dean, Zanders, and Bailey 2001; Hopkins et al. 2006; Jungmittag, Reger, and Reiss 2000; Orsenigo, Pammolli, and Riccaboni 2001; Webster et al. 2004) and a patent search on pharmacogenomics technologies.⁶ This triangulation of sources resulted in a complete list of companies. A major indication for this was the high level of saturation: new lists barely added new companies to the database. Because we were interested in the positioning of companies towards an emerging, innovative technology we did not include those that were focused on generic products, i.e. products no longer protected by a trademark or patent. Moreover, the theranostics storyline is about the combination of diagnostics and therapeutics based on genetic markers. Other uses of genetic markers include determining the genetic make-up of a virus and thus fine-tune the development of vaccines. Because this involves testing viruses and not the human body itself, we did not include these developments in our database.

Besides different kinds of companies we also included the two most important regulatory authorities in the pharmaceutical world, the US Food and Drug Administration (FDA) and the European Agency for the Evaluation of Medicinal products (EMA),⁷ because they have a major impact on the research and development of innovative products and show great interest in the new storyline of pharmacogenomics (EMA 2003; Ratner 2005).

After constructing the database of relevant companies we analysed all their 2004 annual reports since they provide the platform for companies to state that which they are most likely to pursue (in accordance with the definition of speech-acts given earlier). Our main focus was on strategy, visions and mission statements: in these sections of the annual reports we looked for statements on theranostics.

After extracting statements from the annual reports we initiated three coding activities. These were characterised by an interactive approach: the validity and reliability of the coding scheme and the coding itself ('interrater reliability') were constantly under discussion. Two researchers each coded a small sample of the database, compared their results and discussed the similarities and dissimilarities. Attention was also focused on the exclusion and inclusion of classes. This cycle of coding, comparing and adjusting the coding scheme was repeated several times. Only when the coding scheme was reliable did the two researchers independently code the total number of statements. Again, the coding was compared and, where necessary, adjusted after discussion.

The first coding activity concerned the grouping of listed companies in five categories: pharmaceutical companies, diagnostic companies, pharmacogenomics companies, the diagnostic

divisions of pharmaceutical companies (from now on referred to as pharma-diag companies),⁸ and regulatory bodies. The third and fourth categories require some explanation. Pharmacogenomics companies are relatively small firms which, in their mission statements, explicitly state that they are engaged in and are founded on pharmacogenomics technologies. Pharma-diag companies are firms that have business units dealing with pharmaceutical and diagnostic products. This grouping of companies was necessary in order to make the claims on positioning on a more aggregated level. In other words, we wanted to analyse the position of pharmaceutical companies in relation to diagnostic companies as opposed to individual companies.

Second, a classification was made of different kinds of statements, namely those that revealed the mere acknowledgement of facts about the storyline, a company's awareness of the storyline, and/or the positioning of self and others within the context of this storyline. Table 1⁹ illustrates such statements, i.e. their definition, hints on how to find them in the annual reports, and examples. These different kinds of statements show some sort of hierarchy of involvement in the theranostic

Table 1. Different statement types.

Labels	Definition	Example
Fact	Piece of information or a statement that is interesting regarding theranostics, but not a realisation of its importance or presence, or a positioning to it. Explanation, co-operations, etc. Verb tenses trigger the reader.	'PathVysion tests for the HER-2 gene in breast cancer patients to identify candidates for appropriate therapy selection, including Herceptin therapy, a targeted cancer treatment' (Abbott Laboratories 2005, 16).
Awareness	Realisation of the presence and importance of personalised/individualised drugs, genetics, genomics, theranostics, etc., but does not necessarily feature in the strategy of the company. It is more an explanation or setting the theme of the text.	'As each patient's response to a drug is different, it is vital to reflect the genetic variations if individuals in therapies. With the advent of DNA-based tests to measure a patient's probable genetic response to a drug, physicians will be able to decide upon the most appropriate treatment' (Qiagen 2005, 11).
Self positioning	Statement of what a company actively does in relation to theranostics (or related issues; the storyline!). 'We', 'our' and the company name typically trigger the reader. Strategy-related and it is related to the intention for action.	'Scientists at Roche Pharmaceuticals and Roche Diagnostics are working together to develop biomarkers that can be used to diagnose diseases, identify the patients most likely to respond to a particular treatment and help develop new drugs.' (Roche 2005, 12).
Other positioning	Statement of how a company sees other industries/companies in relation to theranostics (or related issues; the storyline!). Again there is strategy and the intention for action.	'We intend to access major international markets, either directly or through partnerships, to support the worldwide marketing of drug therapies for which our tests are relevant, specifically where those drugs have been approved based on clinical trials in which our tests played a pivotal role.' (ViroLogic 2005, 12).

Note: significance of emphasis in table.

Table 2. Fictive example of database entry.

Company name	Page number in annual report	Self or other positioning	Other company (in case of other positioning)	Speech-act (statement)	Script details
X-pharma	3	Other	Diagnostic	We see crucial partnering opportunities with the diagnostic sector for realising our co-development strategy on Drug-Y®.	Tandem

storyline: merely acknowledging the facts surrounding theranostics implies less involvement than awareness of the actual importance of theranostics. In the same vein, merely recognising the importance of the storyline indicates less involvement than actually acting and positioning with regard to this storyline.

Third, when all the statements had been classified as a fact, awareness, or self/other positioning statement, it would be interesting to show what kinds of strategies the companies follow. In other words, what script a company adopts. To do this we looked at the self and other positioning statements because the definitions in Table 1 excluded fact and awareness statements from having a strategy or action-oriented outlook. One example of an entry in the resulting database is shown in Table 2. In the next section we will go into more detail on the different scripts.

In the next section we will delve into the case of theranostics, an emerging technological field that was briefly introduced in the first section. Positioning theory and ways operationalise this to methodologically were introduced in Sections 2 and 3 and thus the next section will explain how the developed methodology works out in practice.

4. Results: the case of theranostics

4.1. Birth and explanation of theranostics

After completion of the Human Genome Project (HUGO) the next step is the era of functional genomics, in which researchers try to uncover which genes do what, when and why, i.e. it involves the biological pathway from genes to their functional proteins. The application of this knowledge in the field of health care and pharmaceuticals is called pharmacogenomics. It is a novel technology field that concerns interindividual differences in gene expressions that are relevant to disease susceptibility and drug response (EMEA 2003).¹⁰ Pharmacogenomic innovations should ultimately lead to diagnosis, treatment, prevention and care that is specific for the genetic make-up of each individual and make drug use more safe and efficacious. Visions of personalised medicine and individualisation of care are connected to the pharmacogenomics future and genetic testing play an important role in that context (Hedgecoe and Martin 2003).

There are two ways of using genetic testing in combination with therapy. First, genetic mutations predict the possible future illnesses a patient might develop. This type of information can then be used to take preventive measures. Second, genetic variations cause differences in treatment response among (groups of) patients. This means diagnostic testing is directly related to therapy. Along this line, several authors of review articles on pharmacogenomics (Ensom, Chang, and Patel 2001; Ginsburg and McCarthy 2001; PriceWaterhouseCoopers 2005; Webster et al. 2004;

Weinshilboum and Wong 2004) envisage a strong relationship between diagnosis, treatment and prevention. Fierz (2004) talks about a ‘diagnostic (Dx) – therapeutic (Rx) tandem combination’, referred to as theranostics. This strong combination is necessary because when a drug is only applicable to one segment of the population it needs to be identified by means of diagnostics. These initial findings are supported by interviews conducted with several key players in the Dutch health care system, pharmaceutical industry and diagnostics developers.

The storyline is thus about the combination of therapy and diagnostics based on genetic understanding – theranostics, which has long smouldered in the academic world and is now on the brink of affecting health care practises. It is growing in importance. We see this from: (1) discussions about the few novel pharmacogenomic practices ‘out there’ and their associated predictions that ‘the age of the blockbuster era may [be] past’ (Royal Society 2005) or more precisely, that the ‘one size fits all’ adage will no longer apply with regard to pharmaceutical products (Marshall 2003; Royal Society 2005);¹¹ (2) the emergence of a new generation of companies, actively using the notion in their strategic formulations; (3) political attention due to the steeply rising prices of new therapies and ineffective prescribed therapies which are no longer acceptable; and (4) the fact that regulatory bodies act by addressing pharmacogenomic issues in position papers and other strategic documents and put increasing pressure on the pharmaceutical industry to include pharmacogenomic data with their (initial) filings (EMA 2003; FDA 2004; Katsnelson 2005).

4.2. *Theranostics and three possible company strategies*

Three possible approaches to the development of theranostics can be distinguished in the literature on current applications and future possibilities in this technological field. They can form part of the strategic visions of companies of the pharmacogenomics future. Strategies are largely sequence-related and can therefore be seen as future scripts, as has been introduced in Section 2. These sequences and the related input from different kinds of companies (pharmaceutical, diagnostics, etc.) are important because they will be the result of or fuelled by their mutual positioning.¹²

1. *First the therapeutic product, then the diagnostic* (‘first Rx, then Dx’)

Patients are exposed to a drug and a differential response to these drugs is recognised. This prompts the development of a genetic test that predicts drug response (Lindpaintner 2001). An example is Iressa (gefitinib), a medicine for treating patients with advanced non-small-cell lung carcinoma (NSCLC). It received fast-track approval by the FDA in 2003 providing that AstraZeneca (the developing company) continued with a large-scale clinical trial. This trial failed to prove the efficacy of the drug and therefore AstraZeneca and the FDA decided to take the drug off the market. Later, researchers discovered that patients in whom Iressa shows a beneficial result have a certain genetic mutation. These results led AstraZeneca to develop a diagnostic test in co-operation with a diagnostic company that will help to detect the presence of certain genetic and proteomic mutations in patients with NSCLC. This is also called the ‘product rescue’ route (Little 2005). Another example might be testing the genetically dependant activity of drug metabolising enzymes, such as CYP450 chromosomes. A CYP2D6 test has been developed and is now awaiting FDA approval.¹³ This test can be applied to all drugs that are affected by the specific drug metabolising enzyme and is therefore a test that is applied to existing drugs.

2. *First the diagnostic product, then the therapeutic* (‘first Dx, then Rx’)

A new diagnostic tool is developed that can differentiate between different patient and disease classes. Doing this will stimulate the filling-in of these classes by creating therapeutics

(Lindpaintner 2001). This is also referred to as the ‘independent’ vision (Little 2005) because diagnostic companies develop tools independently from pharmaceutical companies. An example would be the stratification of complex diseases like cancer, schizophrenia or Alzheimer’s disease into subcategories using diagnostic tests and the subsequent search for therapeutics in each area.¹⁴

3. *Co-development of diagnostic and therapeutic product (‘tandem strategy’)*

The development of diagnostics and therapies can occur in tandem, as was the case with Herceptin and HerceptTest. Genentech, a US biotechnology company, was developing a drug called Herceptin (trastuzumab), a monoclonal antibody to treat metastatic breast cancer. They soon discovered that the drug was far more efficacious on patients who have an over-expression of a protein receptor (HER2). In early 1998, Genentech approached Dako,¹⁵ a Danish diagnostics company, to develop a test to diagnose this over-expression. It is believed that regulatory approval was given because of this matching of therapy and diagnostics (Knowles 2004). Finally, the FDA approved the diagnostic test and the drug simultaneously in September 1998. Since then, the FDA has been investigating this drug and diagnostic development route, which in March 2005 led to the release of a paper on co-developing gene-based diagnostics and therapeutics (Katsnelson 2005).

Figure 2 shows how these strategies link up with the development pipelines of both industries.

4.3. *If and how does the industry react to this theranostics storyline?*

Three existing groups of companies and one emerging group of companies are active in the future shaping of the theranostics tandem, namely pharmaceutical companies, the diagnostic divisions of pharmaceutical companies, diagnostic companies, and the ‘new boys’, pharmacogenomic companies. In the present and past state, the pharma-diag companies were unrelated to their pharmaceutical parent, but how will they react to the rise of theranostics? How will the ‘old’ diagnostic companies react? How do the new pharmacogenomic companies position themselves in relation to the pharmaceutical companies? How will the pharmaceutical companies deal with the need for theranostics and tailor-made medicine? We will investigate how these

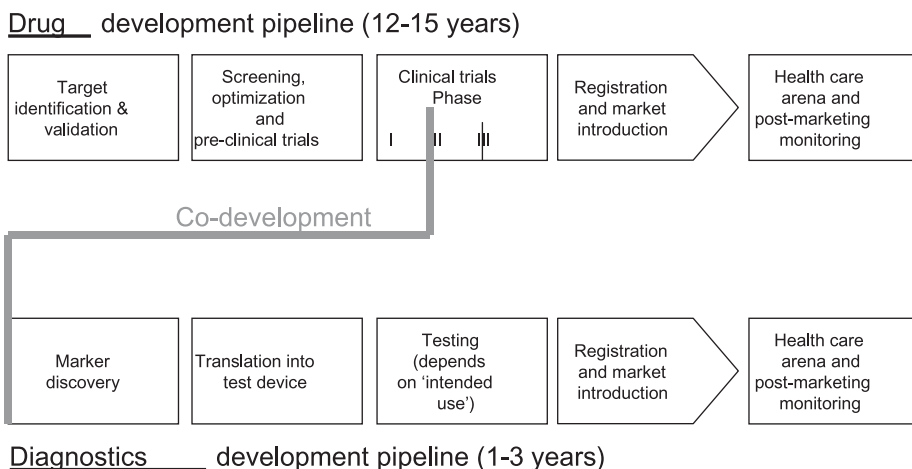


Figure 2. The pharmaceutical and diagnostic development pipeline.

companies try to gain a position in this emerging field by using argumentation related to the three developing approaches recognised. By doing so, we aim to gain a better understanding of the present day dynamics in the emerging theranostics field that will shape the (future) strategies of companies.

Theranostics is a combination of two, previously unconnected, fields or worlds. Both fields have their own players and dynamics and are now on the brink of entering into a fully-fledged strategic game. One might add that this strategic game gains in importance for the participating actors because it is expected that the actor who becomes in control of the ‘theranostics’ tandem (i.e. those who will dominate the diagnostics and the therapeutics of a particular disease) will benefit the most. Therefore, a strategic position in this field is seen as important (Little 2006).

4.4. Results

To obtain an overview of the dataset as used in this study, Figures 3 and 4 show the number of actors by category and origin. Pharma-diag companies are diagnostics divisions of pharmaceutical companies; therefore, their parent companies are also listed under the category of pharmaceutical companies. We see that the majority of companies are based in the USA. In addition to these more descriptive results, this section will also show whether the perspectives of companies on the industry structure are affected and if so, are shared perspectives to be identified within one category of companies?

Whether the industry *does* react to the storyline can be seen in Table 3,¹⁶ which gives an overview of the kinds of statements expressed for each category of companies. It can be seen that for the pharmaceutical companies, the percentages of self and positioning are relatively low compared to the other categories. More than half of the pharma-diag companies are aware and even 50% position themselves, but they do not show any other positioning. By definition, the pharmacogenomics companies are all aware and about half of them actively position themselves towards the storyline. In terms of positioning, the pharmacogenomics companies almost reach the same percentages as the diagnostic companies. Both regulators are aware and give self and other positionings.

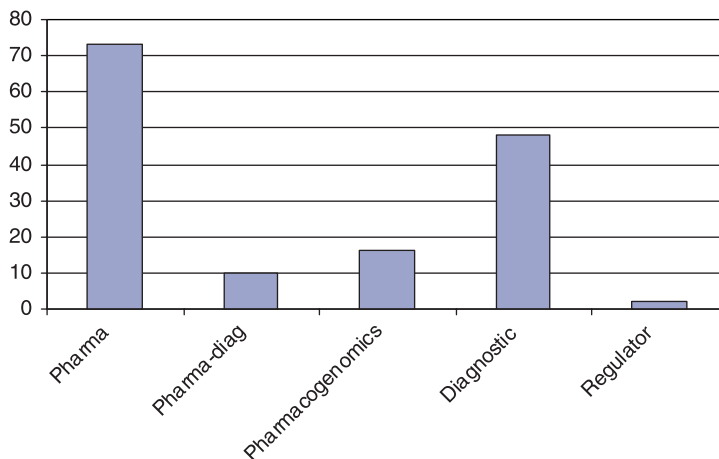


Figure 3. Number of actors by category.

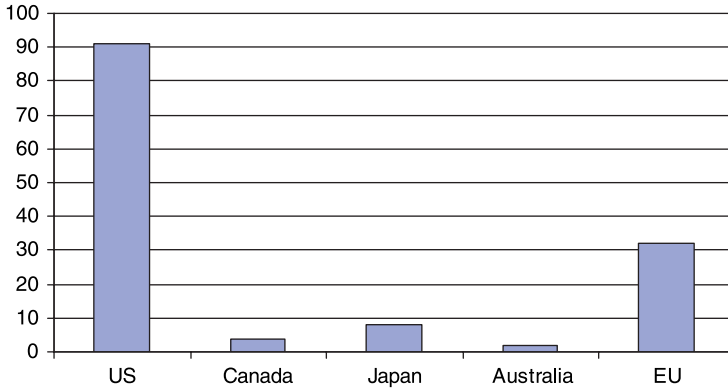


Figure 4. Origin of the actors.

Table 3. Number and percentage of actors in relation to the expression of awareness and positioning. ‘Only aware’ means that those companies do not have self and other positionings. Self and other positionings are not mutually exclusive, meaning that companies with self positioning statements can also make other positioning statements and vice versa.

Category	No expression of awareness	%	Only aware	%	Self	%	Other	%
Pharma	40	55	14	19	12	16	6	8
Pharma-diag	4	40	1	10	5	50	0	0
Pharmacogenomic	0	0	7	44	7	44	5	31
Diagnostic	23	48	8	17	18	38	13	27
Regulator	0	0	0	0	2	100	2	100

To investigate *how* the industry reacts, we take a look at the actual content of the self-positioning statements. We then turn to other positioning to see whether any clear positions surface. We conclude the analysis by comparing the self and other positioning of the different categories. This gives more insight into a field’s current state, in relation to how future roles are envisioned and brought to the fore.

When we look at the self-positioning of pharmaceutical companies, they either seem to go for a ‘tandem’ strategy or a ‘first Dx, then Rx’ strategy. When there is a separate business unit working on pharmacogenomics there is strong emphasis on the ‘tandem’ strategy. Pharma-diag companies focus on supporting clinical practice and therefore take the ‘first Rx, then Dx’ strategy. There is no convergence in the strategies of pharmacogenomics companies as they follow all three strategies. The same holds for the diagnostic companies. Regulating bodies on the one hand promote safety and effectiveness of clinical trials, but on the other hand they have no wish to hinder drug development progress. In clinical trials, diagnostics can be used to select specific target groups upfront, in later stages of the trials, or as a more general diagnostics, for example to monitor the metabolism of the drug. The focus of regulatory bodies is therefore on ‘first Dx, then Rx’ and the ‘tandem’ strategy.

Statements of other positioning can be visualised in a diagram, pointing out who is positioned by whom (shown in Figure 5). It presents a rather unbalanced state of the field in relation to the theranostics storyline. Pharmaceutical companies seldom position the other players in the field,

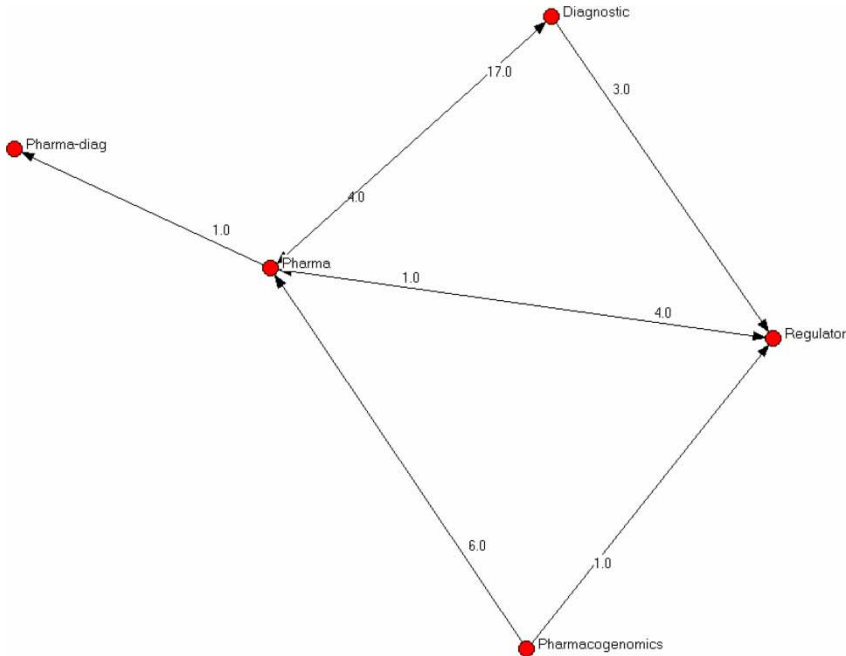


Figure 5. Other positioning. The number closest to the originator gives the amount of other positioning statements. Each company may only give one entry to this data.

while others do position them. The regulators focus their positioning statements on pharmaceutical companies while they are being positioned by others. Pharma-diag companies appear to be outsiders in the positioning arena.

The numbers and directions of positioning in Figure 5 can be combined with the script that appears as dominant after analysing the statements made by these companies. This is shown in Figure 6. We then see that diagnostic and pharmacogenomics companies use the ‘tandem’ approach in combination with ‘first Dx, then Rx’, while the pharmaceutical companies and regulatory bodies focus on the pure ‘tandem’ approach. By adding the word ‘prudent’ to the tandem strategy between pharmaceutical companies and regulators we mean that the regulators are asking sponsors to file pharmacogenomic data, but are not demanding it adamantly.

We broadened the analysis by comparing self and other positioning in categories of companies (see Table 4). This reveals whether the position given by others is in agreement with the role the companies envisage for themselves. It then appears that only for the pharmaceutical companies is there agreement between what they want to do themselves and what others think they should do. If we take a look at the other actors then we see no such agreement. One could argue that because there is no data on some relations, as we saw in Figure 6, it might be less feasible to draw conclusions. Nevertheless, we take a pragmatic standpoint in this respect; if there are no expressions, the situation is not clear and therefore there is no agreement. Furthermore, we see that the pharmacogenomic and diagnostic companies do not share consensus within their groups regarding their self-positioning. Agreement on other positioning is therefore not easily obtained. Nevertheless, there is partial agreement for diagnostic companies with regard to supporting clinical trials (‘tandem’ and ‘first Dx, then Rx’).

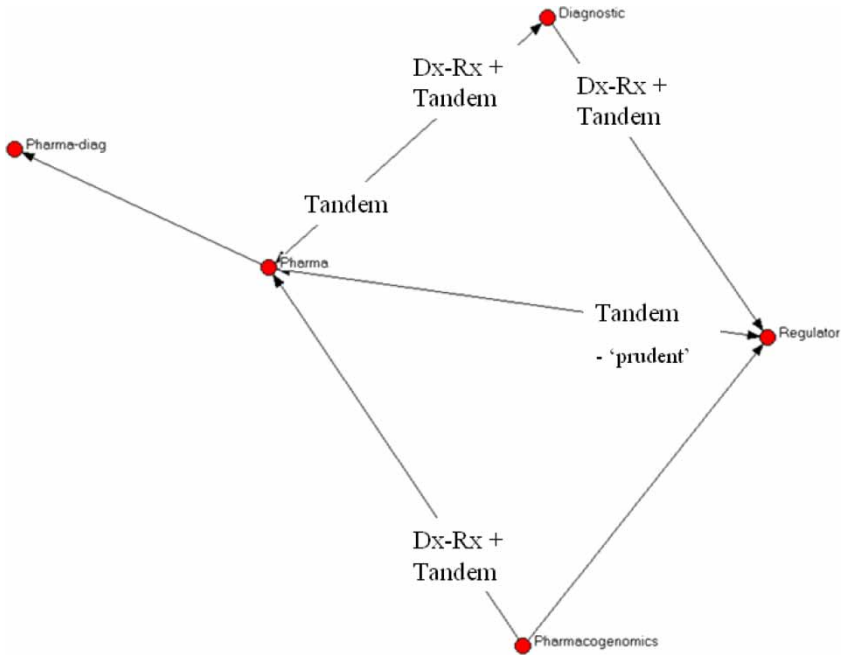


Figure 6. Other positioning highlighting the main script. More than one positioning statement was needed to conclude on the main script.

Table 4. Self vs other positioning.

Category	Self-position	Agreement
Pharma	Dx-Rx + Tandem	Yes
Pharma-diag	Rx-Dx	No
Pharmacogenomic	Unclear	No
Diagnostic	Unclear	Partly
Regulator	Dx-Rx + Tandem	No

To conclude, we see a field that is unbalanced and in non-agreement about the future roles of the actors involved. The field is emerging and consists of old and new players that were relatively unconnected in the past but might become more allied owing to the pressure of the theranostics storyline. Nevertheless, when we look at the envisioned roles as expressed in the 2004 annual reports, companies are relatively aware of the storyline and an active search process on this matter is perceptible. Some insights were obtained in the prevailing strategies that are put to the fore. The ‘tandem’ and ‘first Dx, then Rx’ strategies seem to become more prominent than the ‘first Rx, then Dx’ strategy, although variations between the actors are in evidence.

5. Discussion and conclusions

This last section is divided into two parts. First, we conclude on the case of theranostics, which also answers our research questions. Do newly emerging storylines such as theranostics affect

the perspectives of companies (industrial actors) about the industry structure? If so, how are they affected exactly and are we able to identify shared perceptions within a single type of actor? Second, we discuss the extent to which the broadening of positioning theory to the levels of companies and industry has been successful.

5.1. *On the theranostics case*

When looking at how companies position themselves in relation to the theranostics storyline, we can conclude that roughly half of the ‘traditional’ industry, i.e. the pharmaceutical, diagnostic, and pharma-diag companies, is aware of genomics-related issues. The pharmacogenomics companies, the ‘new boys’, are by definition aware of the importance of personalised/individualised drugs, genetics, genomics, theranostics and the like.

The self and other positioning of these firms reveal another interesting story, summarised in Table 4. Pharmaceutical companies are frequently positioned by others, while they themselves do not seem to need the outside world. The number of statements in relation with the number of companies supports this conclusion: even though there are more pharmaceutical than diagnostic companies in the sample (48 diagnostic vs 73 pharmaceutical) there are far more other positioning statements by diagnostic companies directed at pharmaceutical companies (17) than vice versa (4). The same issue of dependence of or fixation on pharmaceutical companies is revealed when taking the pharma-diag companies into account: they serve their pharmaceutical parents by choosing a ‘first Rx, then Dx’ strategy. This can mean that therapeutics are seen as the company’s core business and diagnostics comes into play when there is a need to support therapy development. Overall, this reveals a somewhat unbalanced situation, which might reflect the historical role of pharmaceutical companies in the field. They could be seen by others as an interesting partner when delving into a new technological field, yet we must be careful not to mix this suggestion with power-related issues because these originally fall outside the scope of positioning theory.

Diagnostic companies are not often mentioned by pharmaceutical companies, while they still hold more opinions on how pharmaceutical companies should behave in the theranostics future. Most strikingly, they envisage that they can play a large role in the clinical trials of pharmaceutical companies. The regulatory bodies do not position diagnostic companies. The reason for this can be a more formal one because historically and legally they focus on pharmaceutical players. At least in Europe, and this is even reflected by the way the organisation is institutionalised; medical devices fall outside the jurisdiction of the EMEA.

Pharmacogenomics companies, which are a heterogeneous group of companies by definition, are not recognised as a separate group of companies that one has to deal with. Also, they are engaged in different kinds of activities, hence the non-converging self-positioning. At the same time, while pharma-diag companies stand outside any discussion, they are internally very important for the leading companies. Again, Table 4 and Figure 6 present a summary of the conclusions we draw from this analysis, but we are wary in making these claims because of the limited number of statements found.

Industrial actors are clearly affected by the newly arising storyline since they address it in their annual reports. Nevertheless, when we look at how this affects the industrial players, pharmaceutical companies tend to leave unchanged their perspectives on the industry structure. They, like the regulatory bodies and pharma-diag companies, still focus on the same actors as they did before the arrival of the theranostics storyline. At the same time, we see diagnostic companies choosing other partners (pharmaceutical companies) in their endeavour to adapt to the storyline. Pharmacogenomics companies remain with no clear common strategy.

5.2. On the application of positioning theory

Concerning the use of positioning theory we can state that it gives detailed insights into the field of study. Moreover, the theory has been applied in two novel ways as was proposed in Section 2, namely: (1) by not only focusing on conversation and immediate interaction as ways of positioning, but also on texts; and (2) by looking at the future. Our tentative conclusion is that both new lines of application show promising results. The theory can be used in a broader field than social situations such as how industry players react to each other under the spotlight of a prospective future situation. This addition is indebted to the used data source, namely, statements taken from annual reports: they almost by definition contain statements on prospective self and other positioning when companies reveal their strategies. As with all data sources, these annual reports also have their drawbacks, for example when companies omit important information for strategic reasons, or when positioning and awareness statements are described in very vague terms simply because an annual report is not really an appropriate medium in which to write about them. Still, we believe that alternatives to annual reports pose similar or other disadvantages. One could, for example, look at (proposed) acquisitions or strategic alliances, but these events are usually initiated after drawing up strategic directions in annual reports and the reasons for these events might be difficult to determine based on information that is in the public domain. For this example, the aspect of timing makes these data less suitable for studying how industrial actors are affected by emerging technological fields.

The theranostics storyline studied in this paper is the starting-point of the analysis, but also of the *de facto* positioning of companies. The plausibility and validity of (following) this storyline is therefore very important. First of all, it should be stressed that we see the theranostics storyline, coming from several sources (e.g. review articles, industry watchers), as a given fact in relation to which a company *should* position themselves. If not, then they will inevitably trail behind the cutting-edge innovative industry players. Second, because discarding a technological option presumes awareness of that option, a company could have made a statement about it in earlier editions of its annual reports. In the same vein, companies could become aware some time later. In both instances, this calls for a longitudinal design of studying positioning towards a storyline. The resultant changing insights are not only relevant for social and economic science scholars, but also, in this particular case, for businesses. Special attention could, for example, be paid to the disagreements between self and other positioning and the related strategies that are found. Companies might learn from them, as well as from the storyline itself. At the same it should be stated that both the researcher and the companies should be critical about the storyline. We started with the 'unavoidable' storyline of theranostics, but there might also be other possible viewpoints and alternatives. Moreover, the storyline itself might evolve as well. This is another reason to strive for a longitudinal approach to studying positioning.

The appeal that we made above for applying the theory and methods behind this study in a longitudinal manner and looking at whether changes occur in the statements, positions and storyline itself does not stand on its own. They are embedded in a more general attempt to capture the envisioned dynamics of an emerging technology in an industry. When studying dynamics one would expect that events are followed through time. In this regard, we not only hope to augment the innovation studies of evolutionary economic studies of technical change and innovation, or to be more precise: the socio-cognitive part of these approaches (as discussed in Section 2), but we also might establish a link with methodological and empirical work. Exemplary in this respect is research conducted by Van de Ven and colleagues on innovation process dynamics; with their 'process approach' they track what they call 'central subjects' through time in a systematic way in an attempt to contribute to existing (qualitative) narrative approaches that study innovation processes (Poole et al. 2000; Van de Ven et al. 1999).

As a final remark, we focused this paper on whether companies position themselves, and if so how, but we did not look at the reason why. For example, a large pharmaceutical company does not wish to cooperate with a diagnostic company because they might be reluctant to share confidential information or because there are power issues at stake. These issues are not dealt with in positioning theory and are therefore not part of the study presented above.

Companies act in emerging technological fields that circulate in and are strengthened by storylines. Positioning theory is a positive inspiration to analyse how, in this context, these companies select their strategies and roles. Furthermore, any storyline is part of a (trans-industrial) moral universe and therefore generally recognised by the stakeholders concerned. A storyline can work out for individual industrial actors in different ways, which we called strategies. Over time, strategies have their pay-offs which in turn interact with newly formed strategies. This results in the evolution of storylines. These dynamics add to (the discussion) 'how' industry players are affected by emerging technological fields such as theranostics, and what roles they play, are forced to play or force others to play.

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Notes

1. Van Lente also contributed to this bridging with his promise-requirement cycles, which say that if a set of actors has a shared expectation on a certain emerging technology, this will create compulsory actions that they should undertake.
2. The concept of script is most notably used by Akrich (1992) who claim that technological objects contain a script that influences or even determines the relationships between users of these objects, and between the users and the object itself. The major difference with the way in which Nootboom applies this concept is the emphasis he puts on the sequence of events that surround the use of a technological object and the subsequent roles actors should play.
3. This, besides being an advantage, contributes to the fact that the discourse studied is a rather abstracted one, as has been mentioned in Section 2.
4. In this regard it was expected that the 2003 annual reports would not yield a sufficient number of results.
5. BioSpace website through <http://www.biospace.com> (accessed 4 June 2005).
6. These patents were extracted from the European and World patent databases (EPO and WIPO) making use of a combination of keywords and IPC classes.
7. We also wanted to include the Japanese regulatory body but were unable to do so because of translation issues.
8. Annual reports of pharmaceutical companies and their diagnostic divisions are the same.

9. PathVysion is a diagnostic test kit. In Table 1 annual reports of Abbott Laboratories, Qiagen, Roche and ViroLogic (all 2004; but published in 2005) are cited.
10. For an introductory description of this field see Hopkins et al. (2006) and Evans and Relling (1999).
11. Some authors claim that a more stratified patient population with matching 'one size does not fit all' products can still lead to earnings that surpass the blockbuster, US\$1 billion mark (Baker 2005).
12. Theranostics is the main storyline, which means a coupling of diagnostics with therapeutics. Two forms of expression are the application of diagnostic tools in clinical trials ('tandem' script or 'first Dx, then Rx'; other script only if it is explicitly mentioned, such as in the case of Iressa) and tests for doctors (mostly 'first Rx, then Dx'; for example, the AmpliChip will be used for the administration decisions of relatively old neurological disease medicines, such as warfarin).
13. This is the Amplichip CYP450 of Roche Molecular Diagnostics (Shastry 2005).
14. The subdivision of diseases in categories might lead to a potential increase of the number of drugs. However, a countermovement can also be discerned: different diseases can be part of the same underlying pathways and in this way require only one common drug (Roses 2000).
15. This approach taken by Genentech makes it clear that this example is not an example of a pure co-development of diagnostics and therapeutics (this might be the case when two companies together start with a certain biomarker that predicts susceptibility for a certain disease). Still, this example is maintained because reviewers see this case as an archetypical example of co-development. Moreover, a drug/diagnostic combination most often emerges in phase II or III of the clinical trials (as in this case) and contracting of diagnostic companies is still seen as part of the 'co-development partnership' vision (Little 2005).
16. The companies that have not expressed any awareness statements in their annual reports (second column) are not necessarily unaware. We cannot claim that; only that we did not find any expression of awareness in the annual reports.

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