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The fog of innovation: Innovativeness and deviance in developing new clinical testing equipment

Maria Höyssä[a,*], Sampsa Hyysalo[b,c]

[a] Finland Futures Research Centre, Turku School of Economics, Rehtorinpellonkatu 3, FIN-20500 Turku, Finland
[b] Helsinki Collegium for Advanced Studies, University of Helsinki, P.O. Box 4, FIN-00014 Helsinki, Finland
[c] Department of Information Technology, University of Turku, FIN-20014 Turku, Finland

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ABSTRACT

Even when innovators know they are working with a potential breakthrough innovation, they face formidable difficulties in assessing the exact ways it will be innovative as well as deviant in regard to extant systems, business and practices. This finding emerges from our case study that spans the 40-year history of an ongoing and by now potentially radical innovation in automated and miniaturized liquid processing. We analyze the changes in the system-to-be and its relationship to its future contexts throughout this period and show how the developers were able to reliably predict technical compatibility, the outcome, the interface points and effects towards the intended environment only some distance ahead. This 'fog of innovation' presents a management challenge not duly met by instruments available in innovation literature.

1. Introduction

The generally held image of innovation is that of a heroic quest for a breakthrough that can disrupt or create an industry and solve society-wide problems. The vast majority of technology projects, however, are incremental. It is towards these that the decades of accumulated managerial routine, instruments and scholarly thinking are geared. Even as there exists a considerable amount of literature on breakthrough projects, 'few empirical studies have identified the idiosyncrasies of the development process for radical and really new innovations and there is considerable anecdotal evidence that radical innovations require unique and sophisticated development strategies, but little empirical evidence to support these theories' (Garcia and Calantone, 2002). Further, most discontinuous innovation processes have been analyzed only when their outcomes and impacts have been readily identifiable. Indeed, the first thing people wish to know about potential innovation—laymen and investors alike—is 'what does it do, what impact will it have?' But what do we really know about how far inventors can specify such outcomes—the value, details and implications of the product—in an early *ongoing* innovation process? Some recent research has begun to recognize this uncertainty (e.g. Duret et al., 2000; O'Connor, 1998), and to underline the management challenge that lies in clarifying what kind of innovativeness—and, by the same token, deviance from extant solutions and markets—the innovation is likely to introduce, as decisions affecting innovativeness can have dramatic impact on the ability to advance the project. We seek to take such work further.

A key problem with the existing frameworks for analyzing ongoing (potentially) radical or discontinuous innovation processes is that they treat the very nature of the innovation-to-be as too evident and stable. For instance, innovation management literature regards the challenges relating to *innovativeness* as being mostly about the ways to frame the appropriate *business* case (Christensen and Raynor, 2003; Kim and Mauborgne, 2005). Most studies with management implications identify organizational structures and practices that would best meet the problems of idea-generation, uncertain markets, competency management in unfamiliar territories, and personality types suitable for advancing uncertain projects in potentially hostile or indifferent environments (Benner and Tushman, 2003; McDermott and O'Connor, 2002; Veryzer, 1998). The various sources of uncertainty and the methods of dealing with it have not been related to the inventions at the core of the project.

In a different line of research, approaches such as strategic niche management (Kemp et al., 1998) and transition management (Smith et al., 2005) stress accumulated capital, economies of scale in production, regulations, consumer habits and often decades of cumulative improvements and additions that allow the widespread extant technologies to 'entrench' against entrants. Targeting the innovation first to niches where selection pressure is less felt is said to allow potentially radical innovations to grow to a point where

* Corresponding author. Tel.: +358 2 4814611; fax: +358 2 4814630.
E-mail addresses: maria.hoyssa@tse.fi (M. Höyssä), sampsa.hyysalo@helsinki.fi (S. Hyysalo).

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they can challenge the sociotechnical regime (Hoogma et al., 2002; Smith et al., 2005; Geels and Schot, 2007). In such studies relating to breakthrough innovations—be they electric cars (Hoogma et al., 2002) or new forms of water management (Hegger et al., 2007), for example—it has been considered evident that the innovation is discontinuous; the crucial task then becomes to learn *which* discontinuous framing might lead to success and how to pursue it.[1] Yet, we argue that in the early stages of *potentially* discontinuous projects it may not be evident whether—let alone which—discontinuous framing would be best suited. Some of the leading proponents of these approaches have started to give attention to the problems that the actors face. In the words of Geels (2004, p. 43): '. . .the multi-level perspective is a structuralist process approach, which provides an overall framework to analyze transitions. The approach needs to be complemented, however, with an actor-oriented approach working "from the inside out". Such an approach would look at how actors try to navigate transitions, how they develop visions and adapt them through searching and learning'.

An emphasis on social, cultural and regulatory (along with technical, organizational and business) embedment comes also from science and technology studies (e.g. Latour, 1996; Callon and Law, 1992; Jolivet et al., 2003) and other detailed case studies of innovation journeys (e.g. Van de Ven et al., 1999). These have given rise to approaches of periodic proactive evaluation for coaching (PROTEE, Duret et al., 2000; Hommels et al., 2007) for project managers (SOCROBUST, Laredo et al., 2002) and key stakeholders (ESTEEM, Jolivet et al., 2008). These approaches seek not only to identify the right people or determine the right framing, but to give tools for learning about the uncertainties in a project and the steps necessary to respond to these to make the project societally better accepted (Duret et al., 2000; Laredo et al., 2002; Jolivet et al., 2008). These tools include mapping the project history and its critical moments, the present techno-economic network (Callon, 1991), the de-facto scenarios of the future embedded in the project (Duret et al., 2000), and relating these to a future network and scenarios of the future working world. These lay the ground for contrasting the project's vision to external checks and clarifying the capacities for action the project has in affecting the concerns that have been identified (Laredo et al., 2002). While these analytics clarify the implications of the project well (Laredo et al., 2002, pp. 54–84; Jolivet et al., 2008, pp. 18–100), the means provided to de-script the future remain vague when it comes to the core of the project. In fact, only ESTEEM categorizes the novelty of each project and while it does this in six dimensions, the studies using the framework have resorted to doing so only once per project, neglecting possible later changes (Poti et al., 2006a,b).

All in all, we suspect that the existing research might have skipped too confidently over a set of thorny management issues about innovativeness and deviance. To investigate this empirically, we ask: *does innovativeness present a challenge for the management of ongoing, potentially discontinuous innovation projects*. With innovativeness we refer to those characteristics of the product that an actor perceives as having novelty-value (and with deviance to such novelty that an actor regards as providing negative value or just added burden). With management we refer to the de facto managing of an innovative project rather than to a specific managerial profession. With discontinuity we refer both to technology and market discontinuity.

We use a single case to make an exploratory study. To operationalize our concern, we ask how the innovativeness of the case project has changed during its development, and what have been the respective implications for the advancement of the project. The case at hand is a rare example of an ongoing project that *intends*, but has not yet succeeded in, launching an innovation that in its present form would be discontinuous both in the technological and market dimension of its respective industry (Garcia and Calantone, 2002). The innovation journey of this 'liquid microprocessor' (LMP) has continued from the 1960s to date with various ups and downs. While the ambition behind the journey—to automate chemical analyses—has prevailed, the focus of the innovation has shifted many times, producing several technical, social and business inventions and framings for the project.

To study the challenges that such shifting innovativeness poses, we deploy two complementary strategies. On the one hand, we provide a narrative from the perspective of the key actors about what they were doing and how they perceived the present and the future of their project. On the other hand, we adopt an analyst's point of view on the project and seek to more conceptually clarify the ways in which the project changed over the years.

The paper is structured as follows: we first clarify our analytic concepts, methods and data. We then proceed to the empirical case, which is divided into chronologically proceeding sections (Sections 3–5), each of which first presents a narrative of events and then an analytical description of the changes. This is followed by a discussion where we link the case analysis back to existing research outlined above.

2. Methods and data

We follow other qualitative studies in innovation in regarding the innovation as a 'journey' that is characterized by contingency but equally by accumulation of solutions and experience (Van de Ven et al., 1999; Pollock and Williams, 2008; Sorensen and Williams, 2002). We follow science and technology studies in discerning the gradually changing visions and re-evaluations, material realizations of R&D, organizational contexts and scenarios of the future (Hughes, 1988; Latour, 1987; Russell and Williams, 2002). We thus study whether and how innovativeness changed during the innovation process by focusing on the developers' changing articulations and understandings concerning the relation between emerging novelties and their implicated contexts. As we outlined in the introduction, there is presently no one analytic available that would characterize the changes in different aspects of the core of the project. At the same time the *findings* coming from innovation studies and science and technology studies indicate four complementary facets of innovation that at least need to be paid attention to[2]:

(1) The most rehearsed of these is the 'degree' of novelty. As is common in innovation taxonomies, we see it as ranging from business as usual to incremental to discontinuous (e.g. Tushman and Anderson, 1986; Benner and Tushman, 2003; Leifer et al., 2000).
(2) The degree of novelty appears different depending on the perspective (Afuaf and Bahram, 1995; Garcia and Calantone, 2002): to whom and in what respect is an innovation novel? For example, a technically incremental application can become

[1] We are grateful to one of our reviewers for clarifying this distinction.

[2] We hence stress that the aspects outlined below are not an eclectic mix from different theoretical positions, but reflect relatively well established findings about different facets of innovativeness. In discussing the 'dimensions' we chose to leave visible some of the alternative ways this aspect has been addressed, but in discussing the other three aspects we identify only the main sources due to limits of space. The sprawl of concepts describing closely similar empirical phenomena used in innovation and technology studies is well documented (for one of the best comparisons see Russell and Williams, 2002) and in the space of this article there is no possibility to properly compare the range of terms by which these aspects have been dealt with in different studies.

a major novelty for a new group of users, or a technologically radical novelty may revolutionize the sub-contracting network but be invisible for the end-user. Techno-economic networks (Callon, 1991) address this issue by differentiating between four poles: technological/industry, science, regulation, and market/users. The CreateAcceptance project expands this to seven dimensions: law and regulation, social, cultural, economic/market, institutional, infrastructural, and technological (Poti et al., 2006a,b; Jolivet et al., 2008; close affinity Hoogma et al., 2002, pp. 28–29). In our appraisal, Lettl et al. (2006) address the issue more clearly with four dimensions that include the 'technological' and 'market' dimensions, the novelty for the organization developing the innovation as the 'organizational' dimension, and the rest of the above listed within the 'environmental and institutional' dimension. This is the terminology we follow below.

(3) Innovativeness may reside in more than one place or 'locus' within and around the product. Changes can occur or be implied in the underlying technological, scientific or organizing principles, components, in the product architecture, in user practices or even in the existing regime. Indeed, structural features have been shown to bear upon the relative ease or difficulty of introducing an innovation (Henderson and Clark, 1990; Gatignon et al., 2002). By dividing the product concept into these loci we can pinpoint where the project's innovative activity—problem-recognition, envisioning, inventing and development work—was focused, and where no innovative activity took place.

(4) Finally, not all techno-economic networks and all their loci are even or alike. 'The seamless web' (Hughes, 1988) is not fully seamless at all times and places, and we found it necessary to distinguish (a) how seamlessly related the dimensions of innovation appear for the developers—for instance how strongly changes in technological details demand changes in the organization of user practices or in the relevant regulatory measures, and (b) how tightly or loosely coupled a system (or configuration) the invention's locus of application appears to be, that is, how seamlessly the product has to fit in with extant instruments and procedures (Fleck, 1993; Russell and Williams, 2002).

The case history is divided into three periods, and following the description of each period we assume an analysts perspective to the developers' understanding of the innovation-to-be, trying to keep *simultaneously in sight* the above four facets of innovation, illustrating the changing loci of innovative activity further in Tables 1–3.

In terms of data we have had access to extensive archival material. There are over a hundred full folders of paper remaining of the project from the period between 1960 and 2008 (if stacked this makes over a 10-m pile!) and in addition over 4000 electric entries on hard drives from the years 1994 to 2008. Typical items are patents, contracts, reports, inquiries, technical reports, correspondence and newspaper clippings. We chose to intertwine the document analysis with a total of eighteen semi-structured interviews of 1–3 h in length, dozens of email exchanges, as well as informal chats and short conversations over the phone and face-to-face. The main innovator was formally interviewed eight times, while other stakeholders formally once or twice. From 2005 on we also have notes from the direct observations of meetings, funding negotiations, technical work, et cetera, as the first author has been an observing and commenting participant in the process.

In the document analysis we followed the principles of historiographic source criticism (e.g. Tosh, 1991) in which we have formal training as both authors have an MA in history. Interviews were analyzed by content, and the views of different actors were systematically compared (Silverman, 1993; Kvale, 1996). Further data and method triangulation was used in comparing the interviews and documents (Denzin, 1989). The analysis proceeded as follows: we first sketched the rough outline of the process with multiple interviews with the key inventor and then searched documents related to the key events and interpretations. The next step was to conduct a round of interviews with eight stakeholders and intertwine these with further document analysis. The preliminary outcomes were several chronologies and narratives of the process, which we gave to our informants for comments, including the draft version of the present paper. A further round of interviews and document analysis ensued in response to reviewer comments—while most of this merely confirmed previous analysis, it did provide a somewhat better position to clarify the early visions of the LMP in the 1970s and 1980s.

3. From a technically discontinuous small-market innovation to a potential breakthrough

In this first empirical section we describe the origins of the technological discontinuity. In the end of the section, we analyze how the locus of the innovative activity moved from one application to another, and diagnose the developers' perception of the meaning of the shift.

The line of inventions began with frustration with human errors. The inventor, while doing laboratory rat tests in 1966 at the University of Turku, Finland, discovered that the method of manual sample preparation severely compromised the accuracy of measurements. He invented a metallic microstructure that enabled a hundredfold improvement in accuracy as well as the automation of sample handling. A representative of U.S.-based SCINS [Scientific Instruments] visited the lab, and, on understanding the situation, provided a grant to build a decent prototype. This eventually led to three generations of 'Sample Oxidizers', which formed a technically discontinuous but market-wise continuous innovation for SCINS and came to dominate the market in sample preparation soon after the introduction of the first generation in 1969. As the development was done abroad, SCINS never integrated the project into its internal R&D department, but funded a small Advanced Instruments Research Group (AIRG) in Finland wherein know-how of the new technology remained.

The group dreamed of a further all-purpose automated method that could provide unforeseen accuracy in chemical analyzes. The solution was to be a miniaturized closed system akin to the Oxidizers. The problem was to find a suitable valve for controlling the liquids on a micro scale after all the mechanical ports, tested in the Oxidizers, turned out to leak or retain dead volumes of liquid. Then chance favored a prepared mind: an Oxidizer blew up an entire laboratory in the US in 1972. Trouble-shooting revealed that users' alterations had caused one of the tiny tubes (1 mm in diameter) to freeze. Melting such a clog required 2000 bars pressure in its −20 °C state, or great amounts of energy and time if done by heating the whole system. The damned clog was an incredible plug! Yet it was evident that very little energy would be needed if there was a way of applying heat directly to the clog. The idea of an ice-valve dawned: whereas existing technology used gravity to keep liquids in open vessels during analytical steps, liquids could be controlled by freezing and thawing ice plugs in the closed microfluidic environment. With this radical invention the group's dead-end was conceptually solved in 1973, and by 1977 the group had concluded that it would be possible to build a generic 'liquid microprocessor' (LMP) for the automatic processing of extremely small liquid volumes.

Enthusiasm was high. The LMP seemed to offer significant advantages by removing manual errors from analytical steps '[i]n clinical chemistry laboratory [due to]:

Table 1
A shift in innovative activity from Oxidizers to the LMP project. The locus where the original problem was perceived to be is marked by *. The locus of the envisioned product is marked by ¤. The main loci of development work are marked by #. *Italics* mark envisioned but not completed work; brackets () mark loci that were assumed not to require innovative work.

Locus	Oxidizer in 1970	LMP by 1977	For comparison: respective elements in conventional clinical testing
Regime/sector	(Biochemical scientific research)	(Health care, water management)	Health care/Clinical diagnostic process
User practice	*(Measurement of radioactive markers in research laboratories)	*(Any practice utilizing chemical analyses, esp. clinical laboratories)	Clinical laboratory
Artefact	¤(Sample Oxidizer)	¤(*Analyzer*)	Laboratory analyzer
Artefact subsystems	Electroformed channels for processing liquids and gas	¤*Liquid microprocessor*	Various mechanical subsystems for performing the analyzer functions
Components	#Commercially available, unsatisfactory valves	#*Electroformed channels for ice valves*	Test tubes & cuvettes (for containing and moving liquids)
Principles	Automation	*Automation*	Mechanization
	#Mechanical valves	#Phase-change valves	Liquids kept in test tubes by gravity
	Closed system for liquid–gas processing	*Closed hermetic system for liquid processing*	Non-hermetic system for liquid processing

1. Greatly reduced costs/test, because microvolumes of the present reagents used. A huge gain in cost/speed. Ten times the speed of any present autoanalyzer.
2. Reduced general costs, because of less negative tests.
3. Better quality control, reliability.
4. Less laboratory manpower.'[3]

Indeed, the LMP appeared to represent a leap in long-standing attempts at reconciling 'the two fundamental and inherent contradictions [of clinical chemistry]: (1) to use as small a sample as possible or available, without exceeding the limit of detection; and (2) to achieve speed without sacrificing precision of analysis' (Rosenfeld, 1999).

These visions were closely bound to the dawning capabilities of the system—they were no fantastic leaps in this regard. 'Every single important aspect of this functional system based on SVV [LMP] has been shown or tested in bits and pieces in AIRG laboratories since 2nd September 1972.'[4] However, the vision's relation to the constraints and requirements of the application domains remained unspecified. An enormous business opportunity was expected from a bundle of generic improvements: '[t]he number of hospital days per patient can be reduced. . . in emergencies very fast [diagnostic] action can be accomplished'.[5] As recognized by the key innovator himself: 'This list [of potential applications] is endless but I have not put too much time in systematically studying it.'[6]

At this stage, we wish to take an analytic look at the innovativeness of the project.

The developers had first-hand experience of the research laboratory, which formed the locus of user practice (see Table 1) where cumbersome manual sample preparation had emerged as the problem driving the Oxidizer development. In the LMP project, the relevant industrial field changed from scientific instruments to clinical diagnostic equipment. The motivation was to eliminate the sources of inaccuracy introduced by manual user practice in all (bio)chemical testing, but the locus of the respective product was unclear: it was first without elaboration, then conceived of as an artefact subsystem ('LMP system'), and later an artefact ('LMP analyzer'). Table 1 presents the shift of innovative activity from the principles, components and subsystems of Oxidizers to those of the LMP.

The nature of innovativeness the LMP product would introduce remained loosely articulated. This was partly because the developers were not aware of the differences between scientific and clinical laboratories—neither had they developed instruments for clinical use. Regardless—or perhaps because of this—the LMP was assumed to turn into a generative innovation that would transform a much broader and more complex locus than the Oxidizers had done.

The type of envisioning done in the LMP project has been found typical of early stages of 'promising technology' (e.g. Lente and Rip, 1998; Russell, 2006). A strong, even hyperbolic trust in the capabilities of the promised technology and capabilities to produce it are conveyed to enroll supporting actors. The envisioning of applications is without much precision or certainty and builds on advances in other fields as well as yet-to-be-articulated requirements and constraints of particular business applications. Indeed, the *degree of novelty* of the LMP technology became articulated only in the *technical dimension*, where its discontinuity was evident. The visions entailed innovativeness in other dimensions as well, but there was little consideration of the exact implications. Similarly, the choice of clinical chemistry as the primary application area—as opposed to water management, which was also considered—was partly due to the developers' view that an advance in clinical instrumentation could have far-reaching effects (in our analytical terms the field was regarded relatively *seamless*), but the exact manner of how the LMP was to fit in was shrouded in the mist. In fact, the next phase in the development work reveals that not even the tightness of couplings between the components *internal* to the LMP could be anticipated before they could eventually be tested.

4. Dawning of business, science, manufacturing and usage discontinuities

In this second part of our case analysis, we show how the downside of the technological discontinuity gradually became evident for the developers as they learned that the innovativeness of the LMP was regarded as a valueless deviance in the wrong direction.

SCINS' competition in sample preparation equipment, chemistry and supplies evaporated during the 1970s. The firm had little interest in funding an uncertain, long-term innovation project for clinical use. The inventor left SCINS, recovered his ice-valve patents and started his own company in Finland in 1977. After a successful line of innovation, there was a strong sense that it would only be to SCINS' loss not to jump on the emerging bandwagon. Negotiations with several companies progressed frustratingly slowly until the marketing department of a U.S.-based computer company with an interest in the diagnostic industry made

[3] Document "Revolution in health care by SVV [LMP] systems', dated 5.6.1977 (beginning) and 14.7.1977 (end), written by the main inventor to convince SCINS to fund more R&D.
[4] Ibid.
[5] Ibid.
[6] Ibid.

an offer of $5.5M. The intention was to design '*a blood chemistry analyzer*'.[7]

Instead, however, the inventor accepted a competing offer from Finnish TEL [Telecommunications and Electronics] and MUF [Multi-Field]. They had been following the inventor's negotiations with the large U.S. company and, at the time, had stakes in diagnostic equipment. The joint venture was '*to develop micro-electro-thermo-fluidic equipment products and sell sub-licenses*'.[8] The financiers' explicit agenda was cost savings, '*The removing of mechanical parts was the advantage; [an analyzer] is cheaper to produce when there are no moving parts. . . We did not see that it would differ from existing analyzers in other respects*' (Interview with the main inventor 5.4.2008). Nevertheless, the inventor's 'hidden agenda' was to improve the accuracy of chemical analysis by automation, as he had done in sample preparation already.

The development progressed through new problems and inventions. A novel reagent package was patented (filed in 1985) and a centrifuge was integrated to the apparatus in 1986. Then ice valves needed improvement. TEL had insisted on using its existing construction technology and materials, and MUF its own production methods. Only after TEL withdrew from the venture in 1985 was it possible to return to developing the original Oxidizer-type materials and create operable channels by 1990. More precision was now needed in liquid dispensing, and it was gained by 1996; and, once the opening of ice valves was reconfigured by 1999 through the use of by then commercially available cheap lasers, the inefficiency of the heating was solved too, clearing one of the final major technical issues.

All in all, it was gradually realized that in order to benefit from the increased accuracy, an increasing number of the analyzer functions (such as dispensing, mixing, incubation, measurement and washing) needed to be built anew just for the LMP. Towards the turn of the millennium it became evident that the performance of the LMP was useless if samples and reagents came, *at any point* in the analysis, into contact with air. The gradual creation of an alternative, fully hermetically sealed system was slow, as all components related to liquid handling had to be developed in-house.[9]

However, difficulties in the business, organizational and environmental dimensions of the innovation overshadowed technical advances. These began with the incumbent patron company MUF already during the 1980s. The diminished use of reagents became an issue for the parent company, as reagents were its main income. Later, it dawned that the hermetic, closed nature of the system made the role of the laboratory, the customer, somewhat questionable, as the LMP in effect attempted to black-box the work done in the laboratory. Besides, the LMP was incompatible with central laboratories, which used parallel processing of samples whereas the LMP could analyze just one sample at a time. MUF insisted in its monthly reviews that the LMP must be used to improve conventional technology, but no such initiative paid off. The performance of the technology was considered too good and the investments already made too significant to discard lightly, however.

Continuation became possible as the development of the LMP was, for a time, paid for by other firms that hoped to use the LMP in their analyzers. But, eventually, there emerged a sense that integrating the LMP to the existing systems of the clinical laboratory would produce endless technical solutions without a marketable application. Eventually the company got a new majority owner, the LMP was shelved and work focused instead on an add-on innovation to the LMP, the 'bellows dispenser', which had resulted from the efforts at hydraulic dispensing.[10]

Another disappointment came from scientific audiences. The technological commitments defined the range of questions that were scientifically or otherwise interesting for conference audiences: scientists in microfluidics dismissed the LMP for not being based on silicon (the evolution of this line of microfluidics is described in Robinson and Propp, 2008), while experts in laboratory automation considered the LMP a hoax. The claim of negligible 0.001% carry-over (from one liquid batch to another) was deemed outrageous, since the laboratory experts knew that (all other) microfluidic structures were flat (rather than round), and absolutely not cleanable. The inventor failed to communicate that cleaning became possible through the hydraulic principle, the zero dead volume, etc. '*The problem was that there had emerged phenomena for which there were no words, no concepts. When explained with old concepts those phenomena appeared as lies, they didn't fit, they were impossible. There was a whole chain of phenomena and operations that one should have been able to communicate, but at the time we hadn't yet formed those concepts, so everyone thought that we must be cheating*' (Inventor's telephone comment on the article manuscript 23.1.2009).

The full scope of the disjunctive features of the LMP began to dawn when the owners wanted to sell the LMP patents in 2000, and failed miserably. The inventor, together with an outside consultant, met representatives from various diagnostic companies. They were often initially interested, but invariably changed their opinion, some explicitly claiming that the invention would destroy their business.

Let us again assume an analyst position to clarify the changes in the innovativeness and deviance the project was perceived to introduce. Throughout the 1980s and 1990s technical incompatibility caused more and more of the analyzer functions to be incorporated into the LMP (see Table 2). This, in turn, revealed that the LMP might turn out to be business-destroying in the *market dimension* for the patron company by undermining its sales of reagents and other equipment. Further, the LMP's serial rather than parallel drive was incompatible with how the clientele (clinical laboratories) organized their practices, which might, in turn, demand seeking new clients. The LMP also threatened to become competence-destroying in the *organizational dimension* by making obsolete the competencies of MUF in other clinical products such as reagents and disposables. In the *environmental dimension*, other incumbents and potential patrons as well as scientific communities connected with clinical chemistry remained doubtful of the innovation.

Table 2 illustrates how the technical novelties accumulated while the product concept came to a dead-end. The gradual work with developing artefact subsystems and components for 'airless' analyzer functions was only enabled by the innovative broadening of the principles on which the system was based. The net result was that the hermetic solutions began to form their own development pathway increasingly separated from conventional clinical chemistry equipment. Meanwhile, despite accumulating inventions, the LMP project partners lost consensus about what problem the LMP

[7] According to an agreement proposed by the computer company on 1.3.1979.

[8] Agreement between TEL, MUF and the inventor's company. 4.4.1979.

[9] For example, in the conventional dispensing method (syringe + flexible tube + probe) sample and reagent are separated by an air meniscus in the tube. But air compresses by six orders of magnitude more than liquid. The functionality of the LMP required the removal of air, because the volume of liquid that enters the system had to be measured with much more precision. In theory, six more digits were possible in a hermetically sealed environment. But there was an even more fundamental reason: any presence of air in LMP channels whose diameter is measured in fractions of a millimeter introduces powerful surface tension and capillary forces—as a consequence liquids move erratically. A hydraulic, airless, dispensing method had to be invented.

[10] The dispenser could also be used independently for accurate dosing of small amounts of liquids. The dispenser was highly durable, which meant that it would have cut MUF's after-sales of disposable syringes and was only commercialized under the next majority owner—in close affinity to the fate of some other LMP parts.

Table 2
The rise of a 'hermetic pathway'—the fall of a product concept. The locus where the original problem was perceived to be is marked by *. The locus of the envisioned product is marked by ¤. The main loci of work are marked by #. *Italics* mark envisioned but not completed work; brackets () mark loci that were assumed not to require innovative work.

Locus	LMP by 1980	LMP by 1990	LMP by 2000	For comparison: conventional clinical testing
Regime/sector	(Health care)	(Health care)	?	Health care
User practice	*(Clinical laboratory)	*(Clinical laboratory)	?	Clinical laboratory
Artefact	¤*(Analyzer)*	¤*(Analyzer)*	*Integrated analyzer* → ¤bellows dispenser	Analyzer
Artefact subsystems	*Liquid microprocessor* with extant analyzer functions	#¤*Liquid microprocessor* with some novel and some extant analyzer functions	*Liquid microprocessor* with all novel analyzer functions but reaction measurement	Various mechanical subsystems for performing the analyzer functions
Components	#Electroformed channels for ice valves	#As before + other capillary channels, reagent bags, syringe-dispenser, *better heating method*, *bellows dispenser*	As before + laser heating, integrated mixer-incubator, digital bellows dispenser	Syringe dispenser, test tube, rotating plates, plastic cuvettes, etc.
Principles	*Automatic, hermetic system* for liquid processing, based on phase changes	*# Automatic*, hermetic *and hydraulic system* for liquid processing, based on phase changes *and pressure changes*	As before + based on phase changes and digitally controlled pressure changes	Liquids kept in test tubes by gravity; moved between vessels mechanically. Non-hermetic system for liquid processing

was out to solve, the contexts it implicated in user practices, as well as expectations regarding the product.

Finally, these dimensions of innovation (and the stakeholders involved) at the targeted locus of application, the clinical laboratory, turned out to be more *tightly related* in regards to entrants like the LMP than was expected: the market and distribution of analyzers and supplements was divided among few large incumbents, and the scientific knowledge in producing and using the equipment had changed along an incremental path for a long time (Rosenfeld, 1999). Even when a whole bundle of additional inventions was in place, the LMP's promises lost their potency when it became evident that it would have to challenge the well-serving arrangements in existing instrumentation and business. The potentially increased innovativeness hence turned into mere increased deviance for all the expected audiences.

5. Disruptive framings of innovation

In this final section of case analysis, we focus on how the previous experience enabled the developers to conceive the innovation-to-be from a perspective that expanded its value-enhancing innovativeness, and how to better handle the deviance that needed to be introduced.

As the patent rights were commercially useless, the inventor was allowed to buy them back. But... to what purpose? He decided to focus on all of the technology's strengths: what customer-related issues *could* it solve?

The one taken-for-granted assumption covering the entire clinical diagnostics was that the *laboratory* was *the* place for extracting information from patient samples. Even the existing point-of-care (POC) applications were only *add-ons* to the laboratory, never replacements. But the LMP as a near-patient system might go further. Technically, real-time analyses for one patient at a time at the health care site would not require the parallel drive that the LMP lacked. The LMP system could generate MUF's results for routine tests in just few minutes and with greater, not lesser accuracy than the laboratory. As consumption was extremely low, enough reagents for 6-month use could be stored hermetically within the PC-sized device. The digital pressure and temperature signals of the analyzer would make remote monitoring of service-needs and quality control possible via the Internet. The end-customer benefits would include the possibility of using the same blood sample in follow-up tests, which would, in turn, cut the need for patients to return for new sampling. And neither would samples need to be transported possibly dozens of kilometres to a central laboratory. These benefits were significant to the entire health care system.[11] The real revelation was, however, the business idea: the apparently impenetrable value network of incumbents could be bypassed if the use of the technology was offered as a *service*. The customer would only pay for the tests, not for the device. No laboratory, no incumbent business, no entrenched science or technology would be needed![12]

The inventor decided to form a company, DITS [Distributed Testing Service], for commercializing the concept, applied for a patent for the respective—potentially disruptive—system invention, and convinced two of his brothers to join in to purchase the LMP patent rights and production technology.

But from these assets it was a long way to a functioning diagnostic system with working and appropriate testing servers, ICT-interfaces, and the functions of a central operator, service provider, and so on. A few million euros were needed for prototype-development, as one needed to set up and optimize the serial production method for high quality core LMP components that would function seamlessly together.

In 2000, the inventor approached the telemedicine department of a Finnish teleoperator. There was enthusiasm, but there were also delays and eventually no deal because the operator dismantled its telemedicine department in a merger in 2004. There were numerous other partnering efforts; for instance, a German reagent company, a U.S. based information technology company, two Nordic telecommunications companies, a representative of clinical research organizations, and an Indian company were approached, along with Finnish and EU funding bodies, programs and research institutes.

Different ways to frame innovativeness were tailored according to the needs and resources of the partner-candidates. The selection of these contacts was mostly done on the basis that their interests would deviate from the conventional diagnostic business model but not from those of DITS. For example, the teleservice of DITS was presented as an extension of the teleoperator's existing business, while it remained unclear whether the service model actually required innovative input from the operator in business or in IT. For clinical research organizations the innovativeness of DITS

[11] Many of these ideas were envisioned informally already in a draft of the inventor's unpursued research plan, University of Turku, dated 25.4.1994, but rejected in the LMP company context leaving little point in pursuing them further at the time.
[12] The service-concept was in fact a necessity since the analyzers would need a professional re-fill of hermetically packaged reagents every 6–24 months.

was presented as being in the ability to achieve high-quality testing location-independently, and for a reagent manufacturer it was framed as a possibility for having a new role as a service-providing partner rather than a vendor of bulk products. Conveying such a semi-flexible business plan proved tricky and there were also limits to the finetuning involved: public funding programs often turned out to be targeted towards generally recognized industrial structures and problems and deviation from such aims could not be masked.

The situation was complicated by issues of control. Most partner and investor candidates wished for more evidence from the DITS concept or wanted full control over it, only to be turned down—the developers perceived them lacking the hard-won lessons of the 1980s and 1990s. The partner candidates outside clinical chemistry regarded the terms as too poor or the concept as too alien to justify entering into a new business. No longer surprisingly, the incumbents were not keen to disrupt their own field. At best, a large diagnostic company considered using LMP technology to calibrate its lab-on-a-chip products, but did not want other applications. By 2007, only EU's EUREKA, The Finnish Funding Agency for Technology and Innovation and one reagent manufacturer remained as prospects that regarded the innovation as potentially valuable with respect to their goals *and* would not hinder the management of one or another dimension of innovation. To its good fortune the project received EUREKA funding in July 2008, covering the design and building of prototypes and the initial validation of the system (in total, 50 person-years) crucial for gaining further rounds of investments.

While large-scale funding was being sought, the project survived for 8 years with modest resources, mostly mobilized from the regional innovation environment. In 2005, facilities were found within the bio-incubator of the Turku Science Park, also enabling collaboration with a local polytechnic through student theses, and providing consultants to aid with, for instance, the creation of business plans. A manufacturing company allowed the developers to use its know-how and facilities in the hopes of later producing DITS servers and components. A professional CEO, a project leader, a laboratory leader, and an expert in clinical and laboratory work, who became the next CEO, joined in due to being familiar with either the LMP project or Oxidizers. The users' motivation was to '*advance one's own field*', as one of them put it, being deeply discomforted about the host of logistic and reliability problems—for example, '*tired of the stupid guarding to ensure that lab assistants don't leave the reagent packages too close to the back-end of the refrigerator for the night*' (Interview with the laboratory leader 8.3.2006). These kinds of local resources allowed the innovation project to inch closer to the building of a prototype and clarifying the business-case and customer-value of the concept.

An important aspect of this work was the emergence of technical, conceptual and business 'add-on' inventions that, again, altered the possible ways of framing the concept. To give a better idea of the contingencies involved, let us examine a development path that opened up a new possibility for framing the innovation as a quality control system. This began as a realization that the service concept might not work: while there were reagents that remained stable for months, human control serum did not. Re-filling servers every few weeks at user-sites would have been unfeasible. It was known that the hermetic ice valve would retain the serum 'virtually unopened', extending its life. And, it dawned that the serum did not even need to stay perfectly stable as long as one would know precisely how it changed. Such subtle changes could not have been measured by other means, but the LMP excelled at that. One problem remained, however: where to find an independent point of comparison? To date, quality control had been laboratory-specific. The same sample, tested in two laboratories with identical methods, was not likely to produce precisely identical results. There was only the indirect, labor-intensive standard method for ensuring that control test results were close to reality. However, in the distributed DITS system several servers could be loaded with small amounts of control serum taken from the same lot, hence jointly revealing any dissenting daily control test value before it grew biologically significant. No-one had conceived of the idea of grid-type networking and the use of an identical control serum before, as it was not practically realizable.[13]

The innovation network was increasingly confident and optimistic. This was supported by a prominent diagnostic market research report predicting that the future of in vitro diagnostic industry depends on the emergence of point-of-care testing with performance matching that of a central laboratory test results. The report judged that present technology is too 'stagnant' to power this next industry life cycle.[14]

One issue needed to be solved, though: how to turn quality control into a tangible asset? Guidelines and standards presented themselves as the prime place to turn. The inventor was an observing member in an international working group for guidelines on future quality assurance. While there were wishes that manufacturers take responsibility for risk reduction, the work was actually focused on increasing the number of procedures of the laboratory staff.[15] The ambition of DITS to black-box and automate the procedures performed by people was, in theory, compatible with the aims of the standards, but the means obviously deviated from those required. Very robust demonstrations would be needed to counter the likely incredulity and resistance to such a solution. Thus, once again, the potential way forward was shrouded—this time by the proven techniques and the vested interests of the industrial and scientific experts that informed the regulators.

Let us again clarify the changes in the innovativeness with the help of more analytic terminology. The disruptive framing resulted from accumulated experience from the domains the LMP/DTS concept was to face. When compared with the vision of the 1970s, the new vision articulated far more precisely the innovation's immediate contexts and interface points. In Table 3, the actors' realization that quality control is a critical issue for DITS is analytically recognized as the added 'System/ensemble' locus, situated between the artefacts and users that control the artefacts. The table shows how, while there was only incremental improvement in the underlying LMP technology, its discontinuity with laboratory testing was solved by *expanding the loci of the envisioned product* from artefact to service in the user practice locus, while it started to become evident that innovative activities might have to be expanded even further to prepare the ground for such a product. The laboratory in its present form would be re-aligned with location-independent networked testing, an unforeseen remote quality control method, and a new business logic—thoughts turned towards the diagnostic process at large.

The new inventions involved a relatively high *degree of novelty* along at least some of their *dimensions*: remote quality control was discontinuous standards-wise and organizationally; the service business was discontinuous business-wise (yet location-independent testing was meant to be continuous, even incremental, from the point of view of the doctor who orders tests—the results would be similar but faster).

[13] The International Searching Authority of the Patent Cooperation Treaty found nothing to compromise the novelty of the quality-control patent in its response as of December 12, 2006—meaning that no one had filed comparable claims before.

[14] *Point of care diagnostic testing world markets. Trends, industry participants, product overviews and market drivers*. TriMark Publications. April 2007. Volume TMRPOC07-0416, p. 187.

[15] Clinical and Laboratory Standards Institute (2005), *Proceedings from the* QC for the Future *Workshop; A Report.* CLSI document X6-R. Clinical and Laboratory Standards Institute, Pennsylvania USA.

Table 3
The characteristics and development of the distributed testing service (DITS) system compared with the characteristics of a conventional clinical testing system. The locus where the original problem was perceived to be is marked by *. The locus of the envisioned product is marked by ¤. The main locus of work is marked by #. *Italics* mark envisioned but not completed work; brackets () mark issues that were assumed not to require innovative work.

Locus	DITS in 2000	DITS in 2008	For comparison: conventional clinical testing
Regime/sector	*(Health care: faster clinical diagnostic process)*	*Health care: faster clinical diagnostic process*	Health care: clinical diagnostic process
User practice	*,¤,#*Location-independent testing-service*	*,¤,#*Location-independent testing-service*	Clinical testing: centralized laboratories + point-of-care tests
System/ensemble	*(Automatic quality control)*	#*Quality control by on-line pooling and automatic performing and analysis of quality control test results*	Quality control by laboratory staff
Artefact	*Networked analyzers*	#*Networked analyzers*	Laboratory analyzers
Artefact subsystems	*Integrated liquid microprocessor*	#*Integrated* liquid microprocessor	Various mechanical subsystems for performing the analyzer functions
Components	Electroformed capillary channels where liquids move and ice valves function, laser heating, reagent bags, digital bellows dispenser, integrated mixer-incubator	#As before + prototypes for *the serial production of core components,* refrigerator, insulated cover, *operation control software, nexus to local health information systems*	Syringe dispenser, test tubes, rotating plates, plastic cuvettes, etc.
Principles	*Automatic,* digitally controlled, hermetic, hydraulic and *networked system* for liquid processing, based on phase changes and pressure changes	#As before + *based also on remote quality control*	Liquids kept in test tubes by gravity, moved between vessels mechanically. Open system for liquid processing. Local quality control

The changes in the degree of novelty in different dimensions also changed the expected relation between the actors in the field: this way of organizing routine testing would be free of pressures to centralize it, the customer could be either a laboratory or a health care facility directly—or a licensed DITS service-provider, a role possible both for existing and emerging diagnostic companies.

These recent add-on inventions underscore the problems that result from expanding the innovative concept in the wake of making it disruptive. The business credibility of DITS depends significantly on the new quality control method; advancing it requires demonstrating the technology in practice; to find funding and partners to demonstrate the technology is, in turn, difficult as long as the regulatory and business ambiguity remains; the ways in which the faster testing would affect appointments in future user sites can be anticipated only to a limited extent before field trials. Indeed, when the dimensions of innovativeness turn out to be nearly seamlessly related in all available framings of the innovation, the number of interrelated issues grows, the targets become more and more ambitious and the amount of work still needed grows rather than diminishes, even when the scope and appeal of the overall innovation may be enhanced. There is hence an obvious downside to framing the potential breakthrough innovation so that its locus would expand: it removes some uncertainties but introduces a host of others. Anticipating and clarifying the likely changes in innovativeness and deviance in different configurations and framings of the project hence seems to present an unavoidable and continuous management concern for an ongoing discontinuous innovation project at least throughout its gestation and early development phases.

6. Discussion

Empirical studies of ongoing discontinuous innovation processes, particularly their early phases, are rare. The timeframes of their completion tend to exceed those of typical research projects and all the while it remains uncertain whether the quest will eventually amount to anything at all. Attempts at reconstructing projects before their clear success (or failure) hold, however, potential advantages, since the innovators tend to rationalize their accounts and smooth over the contingencies, idiosyncrasies and retrospectively false turns in typical post-factual accounts (Bijker, 1995). With this in mind, the study of the ongoing and by now potentially radical LMP presents a window onto the emergence and perception of novelty during such a process, allowing us to deepen the understanding of the management challenges involved.

The case analysis revealed that innovativeness posed a management challenge for the potentially discontinuous innovation process in at least two ways, one related to the project's internal dynamics (understanding innovativeness), the other to its perception by outsiders (presenting innovativeness). The project gradually moved into an alternative technological pathway: from mechanization to automation, from an open to a closed system, from gravity-based to temperature-based liquid control, from analogical to digital pressure control, from local to networked solutions. All the while the developers were able to reliably predict technical compatibility, the outcome, the interface points and effects towards the intended environment *only some distance ahead*. This situation was further obscured by what could be called conceptual discontinuity—the lack of accurate terms, concepts, and traditions to elaborate and contextualize the work, the components, and especially the underlying principles. Taken together, these issues formed a long learning process for the developers, and understanding innovativeness has formed, and continues to form, a critical management challenge internal to the project.

The second challenge was related to presenting innovativeness: what the developers considered as technical innovativeness was by outsiders easily perceived as deviance adding complication to the project. The project could only begin to find appropriate kind of support when novel solutions were accompanied with respective market, organizational, environmental and conceptual insight that enabled customizing innovative framings for targeted audiences. How to present innovativeness and deviance thus formed another critical challenge for the advancement of the project. The experience of reconstructing the history of the LMP indicates that many actors in such a project—innovators, associates, investors, managers—lack, almost chronically, the means to clarify the pros and cons of alternative framings, development paths and next steps to be taken. Certainly, they were after finances, resources, advancing their own careers, et cetera, but insofar as the project was concerned all these calculations necessarily involved continued estimations of the innovativeness and deviance of the project—both as a source of potential revenue as well as a source for potential difficulties.

The LMP case thus indicates that knowledge about the way in which a particular invention is radical or competence-enhancing or destroying *can only* accumulate gradually in some projects. In this light, retrospective analyses—whether utilizing innovation typologies or the concept of disruptive innovation (Christensen and Raynor, 2003), or SNM and transition analyses (Ende and Kemp, 1999; Geels, 2002)—by default portray breakthrough innovation projects with unrealistic clarity regarding what the project and its

implications will turn out to be. This may appear as a mere stylistic choice or a matter of convenience. To us, leaving this 'fog of innovation' aside appears more consequential, akin to neglecting the 'fog of war' in military operations.

Let us examine the implications the fog of innovation has for the three literatures on breakthrough innovation we outline in the introduction. In the management of disruptive innovation, Christensen and Raynor (2003, pp. 49–50) prescribe an easy protocol, "a litmus test", for testing the disruptive potential of an idea. However, in the case of technologically discontinuous inventions it can be far from evident where the *locus* of substitution and disruption should be when the development is still ongoing. The disruptive business case cannot be induced or tested before follow-up inventions and accumulation of understanding of the technology have taken place, for these have decisive effect also on its potentials in the market, organizational and environmental dimensions. In the LMP case, the Oxidizer success was followed by the strategy of developing an LMP-based artefact or artefact sub-system for clinical laboratory use and wait for its revolutionizing potential to be actualized gradually from there on. This was rational evaluation at the time. The disruptive idea of bypassing the centralized laboratory would have been science fiction before the Internet, cheap lasers, and a thorough understanding of the present business logic and quality assurance practices were available. Indeed, reaching a point where a 'litmus test' of disruptiveness can be reliably done can require years, even decades, as it did in the LMP case.

The second set of approaches to breakthrough innovation concerns strategic niche management and transition analysis (Hoogma et al., 2002; Geels, 2004; Geels and Schot, 2007). The case analysis underscores Geels' plea for 'an actor-oriented approach working "from the inside out". . . look[ing] at how actors try to navigate transitions, how they develop visions and adapt them through searching and learning' (Geels, 2004, p. 43) to complement the structuralist multi-level perspective (MLP). Indeed, the MLP could offer little for the LMP before the present date. An outside analyst could have stated the obvious about the potential for regime change in clinical chemistry—technology was stagnant and the key interest groups have interlocked interests—but the loci and dimensions of innovativeness in the LMP's confrontations with the clinical chemistry regime were unknowable before the technology was advanced to its early to mid-1990s state. However, during the last 5 or so years when the technological and business implications of LMP technology have become clearer, an analyst could define several niches that offer some, and could perhaps be made to offer more, protection for the LMP and also hold potential for a broader transition. Point-of-care testing in remote locations and quality assurance procedures are not likely to be the only ones here. We are hence inclined to conclude that for instance transition descriptions and the formation of protective niches would become truly relevant to the innovating actors only after much of the fog surrounding the project's innovativeness and its relation to the regime has already cleared. At this point many of the most decisive and vulnerable moments in developing an alternative technological pathway have already passed. We cannot know if Geels had this in his mind in his statement about the need for a complementary actor perspective, but the gestation and early development phases of potential breakthrough projects would seem to a benefit from a different management approach. More exactly, the LMP case suggests that approaches to proactive periodic evaluation could indeed provide a complement to SNM rather than a competing set of means for management challenges that emerge after the earliest and foggiest phase (cf. Hommels et al., 2007).

This brings us to the last set of literatures which we wish to engage with this paper. Socrobust and ESTEEM have taken STS-originated PROTEE ideas of turning high uncertainty to known complexity considerably further in terms of involving multiple stakeholders and in terms of the implementability of the evaluation procedure. They have also provided more sophisticated ways to assess the relationship between the project and context (Jolivet et al., 2008, pp. 30–35). Yet, even though 'de-scripting' the project, including its core, can be considered a major original insight in PROTEE (Jolivet et al., 2003), its means have enjoyed little further development in Socrobust and ESTEEM in comparison to the other parts of the evaluation process. While we have here analyzed the ongoing case retrospectively, we argue that systematically exploring the innovativeness—here done through elaborating its degree, dimensions, locus and tightness of connections—presents a way that could be used to better characterize what is possible and what would be desirable with respect to shifts in the nature of the system-to-be. This, as PROTEE argues, can help to analyze the implications of the innovation's alternative framings for different stakeholders and vice versa. Yet, clarifying the innovativeness and its likely implications requires a great deal of domain knowledge that takes years to accumulate, and hence active network collaboration with for instance, as in the case studied, lead-users and other strategically positioned actors is vital in complementing whatever 'innovation coaching' is to take place (cf. Von Hippel, 2005; Lettl et al., 2006; Poti et al., 2006a,b).

While the innovativeness and deviance of a breakthrough project is impossible to determine for certain as long as the project continues to shift, apt means to clear some of the fog appear to be urgently needed. Such means could well have helped the LMP developers to see already in the 1990s that the key issue was not how to integrate the LMP into existing analyzer functions, but to rethink the requirements and consequences of the full automation of chemical analysis—as well as to argue such a case more poignantly to patrons and investors. Further research on the strategic options of ongoing breakthrough projects just may be more urgently needed than the present literature expects—we know mostly of success stories and little about on-going projects and failures that might not have failed with more adequate measures taken.

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