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Description	一般講演要旨

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Analytical Framework for the Study of the Emergence and Evolution of New Innovation Systems

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Abstract – **The world is now experiencing accelerated rates of technological and scientific change that coupled with on-going societal changes have led to the constant creation of novel technical artifacts. The latter involves the continuous distortion of the innovation system landscape, in which new systems emerge and evolve, established systems change, whereas other dissolve. Such dynamics characterize transitions toward artifactual miniaturization, which define the emergence of a fully-functional, highly miniaturized artifact with the potential to fulfill, in a radical way, the functions currently fulfill by cumbersome, large artifacts. At their heart, those transitions embed process of technological change. Thus, the present paper is an attempt to define an analytical framework to study of the dynamics of technological change taking place in transitions toward artifactual miniaturization.**

1. INTRODUCTION

Miniaturization technologies – micro- and nanotechnologies – are positioning themselves as key enablers in the exploitation of the wide array of innovative opportunities generated by the coupled effect of accelerated technological and scientific progresses in advanced fields of knowledge and on-going societal changes. In particular, our focus lies on a characteristic miniaturization phenomenon: the *emergence* of drastically miniaturized, fully functional, and thus highly portable, technical artifacts capable of (over)fulfilling, in a *radical* way, the functions currently being fulfilled by – in relative terms – dimensionally larger, cumbersome macro-artifacts. The latter defined here as *transitions toward artifactual miniaturization*. Their effects and consequences go beyond 'mere' technological issues to embrace broad-encompassing transformations along multiple dimensions. Such transitions are not new, but their impact and nature have drastically changed; in particular, over time they are pervasively spreading into 'non-traditional' artifacts – that is, beyond the 'traditional' semiconductors-based consumer electronics – such as portable diagnostic devices, miniaturized satellites, miniaturized manufacturing systems, miniaturized chemical plants, among many others.

Typically, such transitions have been visualized as abrupt, isolated, linear, substitutive technological shifts from large artifacts to desktop-sized devices to handheld and wearables to even implantable devices. The latter evidently oversimplifies the complexities behind those transitions by focusing on the end-states, and thus ignoring the whole range of dynamics behind the processes leading to those (temporary) 'end-states'. In view of such situation, this paper is aimed at outlining the basis of an appropriate analytical framework for the study of transitions towards artifactual miniaturization.

This paper is structured as follows. Section 2 discusses the underpinning conceptual background. Following, Section 3 describes the building blocks of the framework of analysis. Section 4 defines and conceptually frames a potential – transition capable – emerging technology, namely 'microfluidics-based point-of-care testing (POCT) diagnostic devices' into the analytical framework defined in the previous section. Finally, Section 5 provides conclusions and lists future research areas.

2. CONCEPTUAL BACKGROUND

2.1. Transitions toward artifactual miniaturization

Two global trajectories for miniaturization technologies may be discerned: (a) the application of miniaturized components or micro- and nanofeatures into/onto large artifacts, e.g. large artifacts with micro- or nanostructured surfaces, nanomaterials-based structure/composition, assembled miniaturized components into large artifacts, among others, and (b) the creation of new, fully functional, drastically downscaled, and thus highly portable, artifacts – in terms of end-products – also defined here as *miniaturized artifacts*. As said, our focus lies on transitions toward artifactual miniaturization, which belong to the second trajectory. Such transitions represent truly watershed events – turning points – in the way the function of an artifact is being fulfilled. Some examples are the early transitions from clock towers to pocket watches, from the vacuum-tube-based computer to transistor-based mainframes and to IC-based minicomputers, from slide-rules to electronic calculators, from furniture radio to portable radio, from fixed photographic camera to portable photographic camera, from fixed telephone devices to cell-phones, among many others. As said, the artifactual landscape is currently experiencing a pervasive spread of transitions toward artifactual miniaturizatrion into a wide array of 'non-traditional' artifacts and fields of applications, such as hand-held bio-sensors and diagnostic devices, mini-chemical plants, micro-factories, miniaturized medical instrumentation, miniaturized satellites, among many others. The latter is radically redefining the miniaturization landscape. Of course, not all miniaturized artifacts embody transitions, as well as not all transitions represent breakthrough events. Besides their high degrees of radicalness – in terms of technology and markets – vis-à-vis the macro-artifact, a critical feature characterizing transitions toward artifactual miniaturization is their potential to shift artifactual capabilities, previously centralized *'in a few hands'*, downstream the value chain toward customers, users, etc.; thus, at their heart they embody a move to technological decentralization, distributed artifactual capabilities, technological empowerment and 'democratization' (Gershenfeld, 2005, Mitchell, 2005, Wright, 2006), see Figure 1, below, as well the broad-encompassing changes involved in the latter.

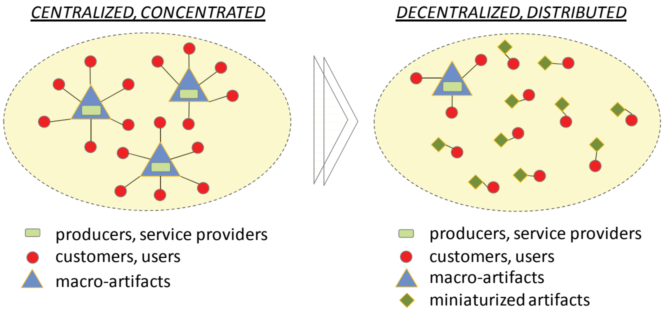

Figure 1 DE-centralization through miniaturization

2.2. Emerging Technologies and Innovation Systems

This paper focuses on emerging, radical, disruptive technologies. Over time, literature has used those terms interchangeably to describe those technologies capable of overthrowing the status-quo. Despite their more or less slightly different meanings, and for the sake of simplicity, this paper will group them into the term *'emerging technologies'*[1]. Technological innovation is inherently uncertain, cumulative and specific, differentiated, and demanding continuous and intensive collaboration (Pavitt, 1990); as such, innovation is seldom the result of isolated and independent efforts, but of complex co-evolving processes involving a network of tightly interacting actors working under an 'institutional blanket' towards the creation, commercialization and diffusion of technological innovations; that is, an innovation system. Innovation systems are constantly changing; they emerge and evolve; they are inherently dynamic, particularly in a largely unplanned manner without following any particular pattern or trajectory (Edquist, 2005, Carlsson, 2003). Over time new systems are 'born', other systems evolve, whereas others mature and dissolve. Here, of particular interest lies the dynamics of emergence and evolution of new, fluidic innovation systems (Malerba, 2005, Carlsson, 2003).

The study of the dynamics of emergence and evolution of innovation systems has been approached in the literature from different perspectives. Typically, studies restrict their analysis of emergence and evolution of innovation systems within the boundaries of the system under study, as well as tend to break down those processes into different stages without delving deeper into the dynamics behind those stages (Phaal et al, in press). Two exceptions are the approaches 'technological innovation systems' (TIS) and 'multi-level perspective' (MLP), which provide richer and broader encompassing frameworks for the study of technological transformations.

A TIS is the structure building around a new technology. It is composed of actors, networks, and institutions. For Jacobson (2008), the formation of a TIS involves three structural processes: entry of firms and organizations, network formation, and institutional alignment. Within the TIS framework, the formation process of a TIS is divided into three stages: formative, growth, and maturation. The formative stage characterizes by its high levels of uncertainty in terms of technologies, markets and institutions, a lengthy process of formation, and by an evolutionary process through the accumulation of small changes, as well as by a search of legitimacy and early premature markets, among others. The growth stage characterizes by the diffusion of the innovations; moreover, this stage characterizes by the continuation of the three structural processes defined above, an increment of the knowledge base, bigger and denser networks, and a higher degree of institutional alignment (Hekkert and Negro, 2008). Finally, Jacobson (2008) argues that changes in the structure and functions of the TIS are the result of both internal dynamics (within the TIS) and factors external to the TIS.

MLP provides a way to visualize the complex dynamics of sociotechnical change. MLP consists of three nested analytical levels (see Figure 2, below): the niche, the sociotechnical regime, and the sociotechnical landscape, representing the micro-, meso- and macro-levels, respectively (Rip and Kemp, 1998, Geels, 2006, among others). Here, the sociotechnical regime embodies the established structure, and thus characterizes by incremental improvements along defined trajectories and by a relative dynamic stability. In contrast, niches embed radical innovation; they depict protected 'brewing' spaces for new – immature, fluidic – technologies. Here, Geels and Schot (2007) define niches as entities with weak structuration, unstable social networks, undeveloped markets, disarticulated cognitive structures, etc; whereas the regime characterizes by strong structuration, stable cognitive rule, alignment, etc. Finally, the sociotechnical landscape relates to external uncontrollable changes, e.g. environmental and demographic, political changes, etc. The critical tenet in MLP states that change or breakthrough is the result of "interactions between co-evolutionary dynamics at multiple levels" (Geels, 2006).

Finally, a series of research efforts have attempted to combine the analytical strengths of different approaches into

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[1] Building upon Day et al. (2000), Cozzens et al. (2010), and Christensen (1997), an emerging technology, in this paper, characterizes by the following properties: new, science-based, novel as how different it is vis-à-vis previous technologies, unique in terms of its dissimilarities vis-à-vis current technologies, impact on future technologies, high-market potential, and characterized by a crude, underperforming nature at their onset.

a single integrated framework. Here, Markard and Truffer's (2008) attempt to integrate TIS-MLP into a single framework should be highlighted. In their approach they operationalize the niche by conceptualizing it as a TIS, which in turn interacts with one or more socio-technical regimes and other TIS of a competitive or complementing nature. Along a more or less similar vein, Steward et al (2008) and Piterou and Steward (2008) conceptualize both the niche and regime levels of MLP as social networks.

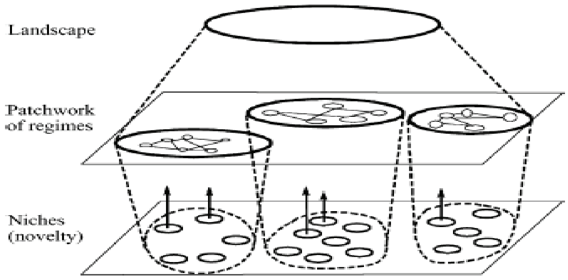

Figure 2 Multi-level perspective model (Geels, 2006)

3. ANALYTICAL FRAMEWORK

The world is now experiencing accelerated rates of technological and scientific progress that coupled with on-going societal changes have led to the unceasing creation of novel technical artifacts, and thus to the continuous redefinition and reshaping of the artifactual landscape. Conceptually speaking, such increase in artifactual diversity involves the 'birth' and growth of new innovation systems, changes or readaptations in the established innovation systems, as well as the possible dissolution of innovation systems. Such dynamics lie at the heart of the transitions toward artifactual miniaturization described in previous sections. Thus, there is a need to understand the dynamics behind such transitions.

Building upon a series of literature sources, this section defines the foundations of an analytical framework for the study of the emergence and evolution of new innovation systems, such as those in transitions toward artifactual miniaturization (see Figure 3, below). Before embarking onto the details of the framework, three general aspects should be highlighted. First, technological change goes well beyond 'mere' technical aspects to encompass changes along a wide array of aspects including social, organizational, cultural, etc. (Geels, 2006). Second, both technological supply and market demand issues should be considered in the analysis of the dynamics of innovation system (Carlsson, 2003). Third, the purpose of innovation systems is to develop, diffuse and use innovation (Edquist, 2005), which is typically oriented toward a specific set of societal functions.

As defined by Rip and Kemp (1998) and Van den Ende and Kemp (1999), novelty originates out of established systems, e.g. based on available knowledge and production capabilities, aimed at solving the problems of the current systems, etc.; moreover, the novel system evolves against the backdrop of the established systems and the environment. The latter implies the dependence of the dynamics of innovation systems on both internal and external factors (Jacobsson, 2008). Within this context, the visualization of the dynamics of technological changes from a multi-level perspective (MLP) 'lens' – as a nested hierarchy composed of niches, sociotechnical regimes, and the sociotechnical landscape – is a logical step. Here, a key concept is the critical role played by the co-evolutionary dynamic interactions *within* and *among* the different MLP levels: niche, sociotechnical regime, and sociotechnical landscape in the dynamics of technological change Geels (2006). Thus, the very nature of those interactions may enhance, inhibit, or have no effect to the processes of technological change.
Here, three aspects should be further discussed: (a) despite

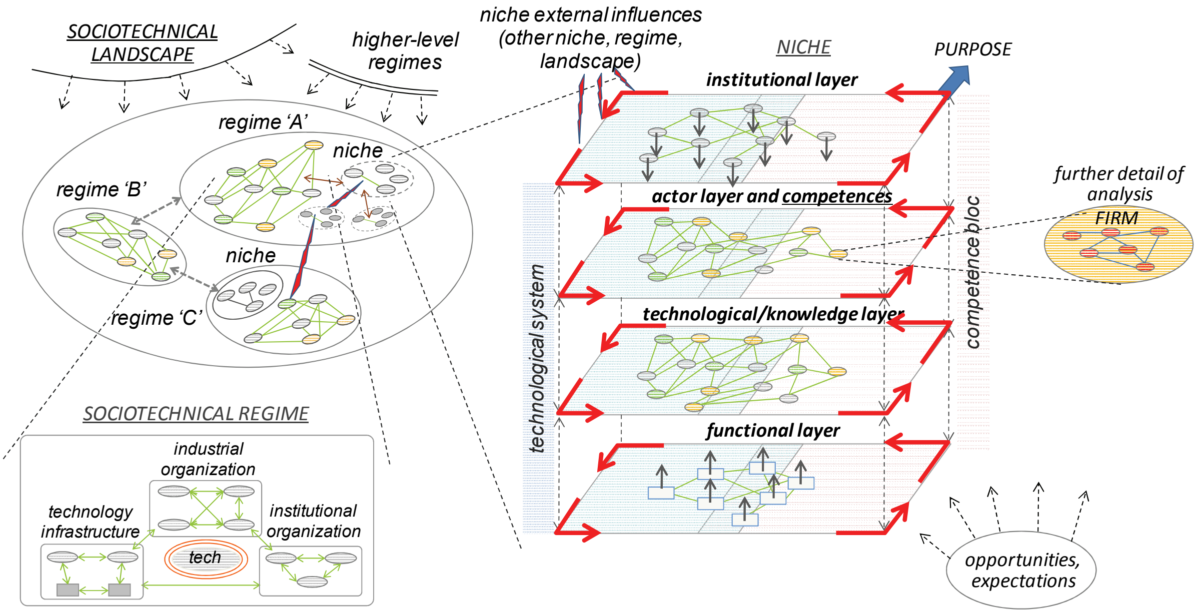

Figure 3 Graphical representation of the analytical framework

their evident stability regimes do change, may be even radically; moreover, they characterize by an adaptive capacity to react to the pressures exerted on them (Smith et al, 2005); (b) at the regime-level, regimes may interact with other regimes located at a same level or at a higher-level, that is they may depict sub-regimes embedded into higher-level regimes; and (c) the nature of interaction among niches, regimes, and niches-regimes may be complementary or competitive.

In line with Markard and Truffer (2008), we conceptualize niches and regimes as 'technological innovation systems' of different, usually contrasting, nature. Whereas the niche embodies a TIS building around an emerging technology, the regime is a TIS rooted in the established technology. As previously seen, niches and regimes differ from each other in terms of market development; network connectivity and density; certainty in markets, technologies, and institutions; development of cognitive structures; institutional alignment; among others. In this regard, niches tend toward instability, fluidity, uncertainty, misalignment, un-development, etc. As such, both niches and regimes characterize by different rates and directions of technical change, embodying different paradigms, following different trajectories, etc.

Furthermore, the proposed analytical framework further operationalizes the concept of the niche-TIS by dissecting it into a set of interrelated, co-evolving layers composed of networks: institutional layer (cognitive, regulative, or normative), actor layer and actor competences (buyer-supplier networks, problem-solving networks, and informal networks), technology and knowledge layer (knowledge base, including artifacts, routines, methods, etc.), and a functional layer which defines how the TIS is behaving along key processes (Bergek et al, 2008). Moreover, in order to stress the importance of both supply and demand aspects the niche as a whole is conceptually divided into the supply-oriented 'technological system' and the demand-oriented 'competence bloc', as defined by Carlsson (2003).

This section has laid out the general structure and characteristics – the theoretical 'skeleton' – of an analytical framework for the study of the dynamics of technological change. However, it is believed that there is still further need to delve deeper into the specific nature of the internal and external co-evolutionary dynamic interactions active in transitions towards artifactual miniaturization, which evidently vary according to the artifact.

4. POTENTIAL CASE-STUDY – MICROFLUIDICS-BASED POINT-OF-CARE DIAGNOSTIC DEVICES

This section attempts to conceptually frame a potential, transition-capable, emerging miniaturization technology, namely microfluidics-based point-of-care-testing (POCT) diagnostic devices into the analytical framework described above. Here, it is believed that such technology represents a suitable prospective case-study of the dynamics of technological change in transitions toward artifactual miniaturization.

a) In-vitro diagnostics (IVD): Point-of-care testing diagnostic devices vs. centralized laboratories

In-vitro-diagnostics (IVD) are tests conducted on samples taken from the human body, such as saliva, blood, urine, among others. IVD spans over a wide range of diagnostic segments such as clinical chemistry, immunochemistry, hematology, microbiology, and molecular diagnostics (The Lewin Group, 2005). Historically, IVD has been conducted by professional laboratorians in centralized, consolidated laboratory facilities in which high-productivity, highly automated, centralized equipment is the rule (Zaninotto and Plebani, 2010). In contrast, point-of-care-testing (POCT) defines highly-portable, miniaturized in-vitro diagnostics (IVD) testing devices which can be easily transportable into the vicinity of patients, physician-offices, home end-users, populations in remote or rural areas (Holland and Kiechle, 2005). As seen, centralized testing and POCT depict different approaches of conducting the same function: to clinically diagnose a fluid sample taken from a human; in essence, POCT represents a paradigm shift.

Currently, POCT takes about a third of the total IVD market. Here, the market is highly fragmented – wide range of application domains – and is particularly dominated by devices for glucose monitoring, blood chemistry and electrolyte, and pregnancy testing, etc.

b) Microfluidics-based POCT

In particular, highly positive expectations are being placed on the application of microfluidics[2], a MEMS technology, in the development of complex, highly miniaturized POCT diagnostic devices. Inherent advantages in the use of microfluidics-based POCT are shorter-times of analysis, small footprints, use of small quantities of reagents and samples, among others

Based on an analysis of journal publications for different MEMS[3] technologies, Figure 4 shows that microfluidics truly represents an emerging technology in terms of its novelty, the speed with which its publications are growing, as well as the accelerated growth rates in the number of papers published in this field (see Figure 4, below)

c) Microfluidics-based POCT conceptualized as a niche

Building upon what has been said so far, it may be possible to conceptually visualize the IVD industry in terms of two main systems: centralized laboratory testing and decentralized POCT.

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[2] Microfluidics " is the science and technology of systems that process or manipulate small (10-9 to 10-18 liters) amounts of fluids using channels with dimensions of tens to hundreds of micrometers" (Whitesides, 2006)

[3] Microelectromechanical Systems

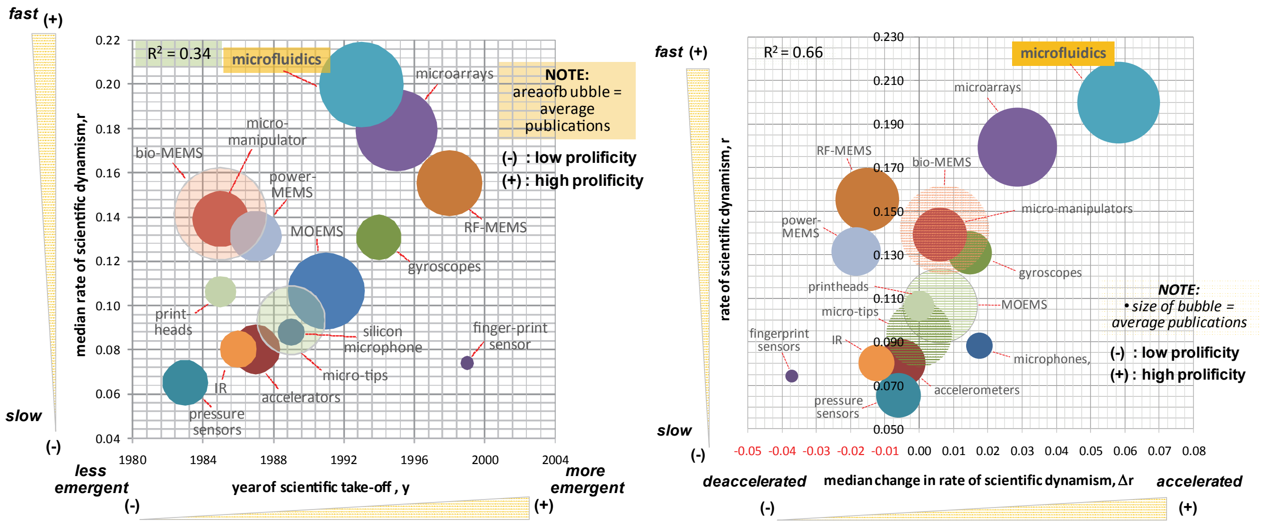

Figure 4 Emerging properties of microfluidics-based technologies

As both systems represent more or less coherent and established structures, they may be regarded as sociotechnical regimes. However, as both regimes characterize by fragmented application domains, the stability and coherence within each of those sub-regimes may vary.

Furthermore, both regimes are by no means isolated entities,; instead, they interact with each other, have partially overlapping interests, and even share system components (institutions, actors, networks). Despite those evident similarities, POCT and centralized testing depict technological innovation systems built around artifacts of a different nature, targeting a more or less similar function – clinical diagnostics – in a different way.

Also, both regimes are contained within the higher-level system "health-care system" and being influenced by external factors embedded in other regimes (complementary or competitive nature), other niches (complementary or competitive nature), and in the landscape.

Further, it is possible to conceptualize 'microfluidics-based POCT' as a niche; as a TIS building around such emerging technology. In turn, the emerging TIS can be conceptualized in the four layers shown in Figure 3. As seen in Figure 5, the emergence and evolution of niche 'microfluidics-based POCT' do not solely depend on the niche's internal dynamics, but also on its interactions with other regimes, as well as its influence from the landscape. In particular, the interaction of the niche-TIS 'microfluidics-based POCT' and the 'competing' regime 'centralized laboratory' should be stressed.

As seen in Figure 5, POCT and centralized testing depict different regimes, which interact with other regimes. As such, both approaches characterize by different technological history, rates and directions of technical

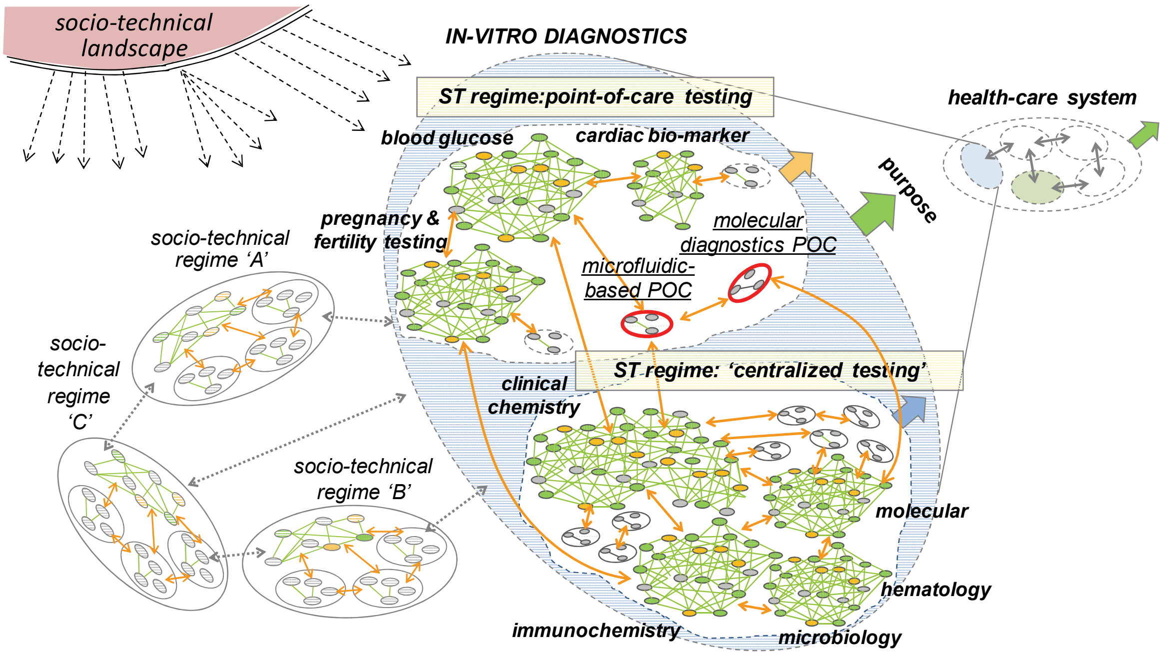

Figure 5 Schematically representation In-Vitro Diagnostics

change, paradigms and regimes, etc. Moreover, both POCT and centralized testing are characterized by different product segments (or application domains) which differ on the way they value artifactual attributes and functionalities. Also, both regimes embed niches. Of particular interest is the niche 'microfluidics-based POCT' which defines the innovation system that is building around that emerging technology. Not only that niche is directly interacting with the regime it is contained, POCT, but most importantly with the 'competing' regime 'centralized laboratory'. Here, there is a whole array of dynamics, internal and external to the niche which come into play in order to have a better grasp on the way technological change takes place.

5. CONCLUSIONS AND AREAS OF FUTURE RESEARCH

The present paper attempted to define the characteristics of an analytical framework for the study of the dynamics of technological change in transitions toward artifactual miniaturization. In particular, this paper focused on the emergence and evolution of new innovation systems. Building upon a series of previous research efforts, it has been seen that an approach integrating MLP and TIS, as defined by Markard and Truffer (2008) coupled with a further conceptualization of the niche into a set of layers composed of networks may prove helpful.

It should be remarked that the approach presented here represents a conceptual, not a descriptive, way to approach the dynamics of emerging innovation systems.

Finally, future research streams are aimed at understanding the emergence and evolution of the niche 'microfluidics-based POCT diagnostic devices'; as well as the nature of the co-evolutionary dynamic interactions among the niches, regimes, and the landscape bringing forward the emergence and evolution of such emerging technology. Building upon that knowledge, it would then be possible to understand the way such a niche-TIS may be further nurtured in order to breakthrough.

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