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Problem-driven innovations in drug discovery: Co-evolution of the patterns of radical innovation with the evolution of problems

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Abstract
A fundamental problem in the field of the product innovation management in biopharmaceutical industry is *how* to explain the general source of drug discovery and radical innovations that sustain the competitive advantage of firms and technological progress in medicine. The current study confronts this problem by developing a conceptual framework of *problem-driven innovation*. The inductive study, based on ground-breaking drugs for lung cancer treatment, shows that the perception and solution of problem is an invariant force that supports the source of radical innovation and evolution of new technology in medicine. In fact, the evolution of radical innovations, driven by the evolution of consequential problems, is one of main determinants that generates a technological change in biopharmaceutical and other industries. This finding, in a Schumpeterian world of innovation-based competition, is due to the organizational behavior of leading firms that have a strong incentive to find innovative solutions to unsolved problems in order to achieve the prospect of a (temporary) profit monopoly. The main aim of this article is therefore to clarify and to generalize whenever possible, the source and evolution of path-breaking innovations in medicine to explain the long-term technological change in society. The study here also shows the important role of data-sharing health policy in order to solve problems and promote innovation for better therapies and an efficient "healthcare ecosystem".

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Overview of the problem in the process of technological innovation

The technological change is a main determinant of economic growth that also induces long-run social and economic change [18,26,27,39][3]. Technological paradigms and radical innovations (i.e. path-breaking innovations) are the main components of the technological change in support of new products and services in markets.

In the field of the management of technology, it is important to explain the source and evolution of path-breaking innovations and *how* economic subjects (*e.g.* biopharmaceutical firms) achieve and sustain competitive advantage with new technology [*cf.* 19,20,28-31,35,59,65, 120]. In general, radical innovation is driven by several concomitant forces that coexist in specific circumstances, and some scholars have described different approaches to explain the source of technological innovation (*e.g.* [119]; *cf.* [24,37,38,62,78]). However, the *general* driving force of the source and evolution of technology is a complex problem, which is hardly known.

The current study confronts this scientific issue by developing the conceptual framework of *problem-driven innovation*, which endeavors to explain and to generalize whenever possible, the source and evolution of new technology in biopharmaceutical industry.

Theoretical background

Dosi [64] (p. 152, original emphasis) states that a technological paradigm is a: " 'model' and 'pattern' of solution of *selected* technological problems, based on *selected* principles derived from the natural science and on *selected* material technologies". Technological paradigms play a vital role in society since they support corporate, industrial and economic change [33,41,48]. The theoretical structure and dynamics of technological paradigms can be described by Teece [125] (p. 509, original emphasis): "Technological paradigms impose behavioral structures associated with 'normal' problem-solving activity. Paradigms imply the use of established problem-solving routines; they indicate where to focus resources and help identify blind alleys to avoid . . . . In short, technological paradigms fill a theoretical void by connecting the market to (at least some) technological possibilities".

In particular, the origin of new technological paradigms is underpinned in basic sciences such as physics, chemistry, and biology [103,136]. These scientific fields support technological advances that can "break-out" current technological trajectories [63]. As a matter of fact, scientific research in basic sciences can spur a faster progress of some technological paradigms, although "relationships between the ability to advance practical know-how and the strength of scientific knowledge underlying that know-how are complex" (Nelson [103], p. 487). Scholars argue that the evolution of science and technology is supported by a process of cumulative change based on the ability to identify, control and replicate practices with "a certain amount of the 'routine' " (Nelson [103], p. 488). This process of (technical) knowledge accumulation is "vital for the growth of effective 'know-how' " (as quoted by v. Tunzelmann et al. [132], p. 479). Instead, Sahal [121] (p. 70, original emphasis) claims that: "the origin of *revolutionary innovations* lies in certain *metaevolutionary* processes involving a combination of two or more *symbiotic* technologies whereby the structure of the integrated system is drastically simplified".

In general, the evolution of technological paradigms is driven by demand factors and technological opportunities, associated to fruitful learning processes [48,64,65,85]. According to Nelson [103] (p. 486ff) a major role in the source and evolution of technological paradigm is played by the "conscious direction of efforts to advance practice, and recognition that efforts . . . are strongly oriented by the body of human know-how to advance practice". In general, patterns of technological innovation are supported by investments in economic and human resources within R&D labs, and by "effective demand" of markets (Nelson [103], p. 487)[4].

Usher [129] proposed a theory to explain the evolution of innovations, using the theoretical framework of the Gestalt psychology (*cf.* [118]). Usher's theory of cumulative synthesis is based on four concepts (Basalla [8], p. 23):

1. Perception of the problem: an incomplete pattern in need of resolution is recognized.
2. Setting stage: assimilation of data related to the problem.
3. Act of insight: a mental act finds a solution to the problem.
4. Critical revision: overall exploration and revision of the problem and improvements by means of new acts of insight.

This theory focuses on acts of insight that are basic to solve the problem. When the stage *two* is set and solution of the problem revised, economic intervention to the process of invention can be effective. The main implications of Usher's theory are the psychological aspects of invention and the evolution of new technology with a vital cumulative change (Basalla [8], p. 24).

In short, the evolution of new technology (*e.g.* technological paradigm) depends on several elements such as needs of society, high economic investment, inventor's act of insight, effective demand, institutional interest, higher democratization, high growth rates of population, major conflicts, etc. (*cf.* [36,38,45,49,52,57,138-140]). A holistic view of the innovation process, based on interrelatedness and interactiveness of social, cultural, economic and political factors, is important to understand the "ecology of innovation" that supports the technological change in society (Marcus [96], p. 446). In general, the role of some factors in the impetus of technological paradigms changes according to the specificity of industries and geo-economic environment.

For instance, technological paradigms in drug discovery industry are generated by complex interactions of demand- and supply-side determinants [1,42,43,50,108] Coccia ([39], p. 271*ff*) argues that scientific research in medicine -to solve vital problems- generates radical innovations (*e.g.* new drugs/therapies) that can be associated, *a posteriori*, with side effects (consequential problems). Some studies have shown that the introduction of a path-breaking innovation in medicine is "probably never the optimal version" and problems (*e.g.*

[3]This study interchangeably uses the terms technological paradigm and/or radical innovation to indicate path-breaking innovations in society [26,27].

[4]*cf. also* Dosi [64], p. 148; [65]; [125].