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Selecting Technological Paradigms: Beyond Push-Pull Dynamics. The Case Of The Artificial Disc

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Abstract:

Giovanni Dosi's technological paradigm theory was developed in part to correct the then dominant practice to focus on either "demand-pull" or "technology push" when explaining technical change. In Dosi's view, demand can act as a 'focusing device' for the supply side to select among the available technological paradigms for development. In this article, we study a specific case, the technological evolution of a surgical implant (an artificial disc in the spinal column), to analyse this selection dynamics. We conclude Dosi's theory can be extended by adding some technological signals interacting with demand forces in this pre-market selection process, which help to explain the historical supply side choices in the evolution of the artificial disc.

Keywords: technological paradigm; focussing device; selection dynamics; technology push; demand pull.

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1. Introduction

Technological paradigms and trajectories are a model of technological evolution analysis proposed by Giovanni Dosi in his seminal work 'Technological paradigms and technological trajectories. A suggested interpretation of the determinants and directions of technical change' (Dosi, 1982), Dosi's framework borrows from T.S. Kuhn's (1962) philosophy of science the concept of paradigm. A scientific paradigm in the Kuhnian sense is a set of theories that define relevant problems, and the patterns and models of the solutions used by 'normal science' activities based on that paradigm (Kuhn, 1962). By analogy, a technological paradigm is a 'model and pattern of solution of *selected* technological problems, based on *selected* principles derived from natural science and *selected* material technologies' (Dosi, 1982: 152, italics in original). The 'trajectories' within this framework are analogous to 'normal science'; technological activity guided by a specific paradigm will form a determined 'technological trajectory'.

The original motivation for Dosi's paradigm/trajectory framework was to criticise the dominant theories of the time, which identified two kinds of determinants of technical change: demand-pull and technology-push. In Dosi's view demand is not, as demand-pull theorists propose, the first motivation for technical change (Schmookler, 1966) However, Dosi also considered that pure technology-push models failed to recognise the obvious importance of economic factors. This push-pull debate finally gave rise to sociological and economic approaches, in which technical change was conceived as a 'seamless web' (Hughes, 1987) of interactions between several factors (economic, societal, politic and technological), which combined to produce functionalities. However, some recent works - although recognising the importance of other factors - focus on demand and technological knowledge as playing the most important roles in

the long term, facilitating comparisons between different fields of technology (Van den Ende and Dolfsma, 2005; Adner and Levinthal, 2001). We follow this tradition in considering imperative to our understanding of the process being studied here to explain the relationships between market signals and technological knowledge-specific elements.

Dosi's position in the push-pull debate is unambiguous: in his view, although demand and other contextual factors can determine the *direction* of technical change among various possibilities, the *sources* of these possibilities (i.e. the technological paradigms) are advances in science and technology (Dosi, 1988). He proposes two roles for demand: (i) demand influencing selection among competing paradigms; and (ii) demand influencing the course of the paradigm after its inception. These roles can be explained using a biological analogy (Dosi, 1984): in the first case, the market acts to select the 'mechanism of mutation' upstream in the initial phases of technological development, that is, to select the technological paradigm that the supply side will subsequently develop. In the second case, the market (understood in a more Darwinian way) is the selection environment for products already developed and commercialised, and this downstream selection shapes the technological trajectories derived from new paradigms. The literature on the paradigm trajectory framework mainly focuses on the second of these selection mechanisms, i.e. the role of the market environment in shaping the precise trajectories of advancement within the set allowed by a specific paradigm. For example, Frenken and Nuvolari (2004) studied the role of user need heterogeneity in the development of different technological trajectories of the steam engine. Instead, the mechanism we study in this paper has received little attention; it describes the role of demand in the selection by the supply side amongst technological paradigms upstream

in the innovation process. One reason for this lacuna in the literature could be the difficulty involved in observing paradigms before their materialisation into marketable devices. An important part of the 'variation' (in the spirit of the evolutionary analogy) on which this pre-market selection process acts is based on ideas; selection in terms of the market environment is more easily observable, as it is based on commercialised devices. Observing variation that exists only in the human mind is a common problem in the broader field of evolutionary economics - in which tradition Dosi is often included (Sandberg, 2007) - and even in general evolutionary approaches to social sciences. As Nelson (2006: 499) puts it 'In cultural evolution a good portion of the relevant variation is in human minds …. A team of engineers contemplates a wide range of plausible designs, and gradually homes in on one, before they actually build and release a new product or process for use'.

However, if we consider the technological 'pre-practice variation' (Nelson, 2006) to be not only the ideas in engineers minds, but also (somewhere downstream of the purely mental realm, but largely upstream of market environment selection) the observable activities of research and experimentation, we can learn more about the empirical functioning of this pre-market selection dynamics. This article will try to show this selection mechanism in operation by means of a case study of the technological evolution of the artificial disc, an orthopaedic prosthesis employed in the treatment of chronic back pain. We will consider how the supply side selects between two technological paradigms of this prosthesis, not in the form of 'plausible designs' in engineers' minds, but in the form of research projects, whose development to become marketable innovations depends on this pre-market selection process, expressed in the success or failure of these projects.

There are no specific indications in Dosi's work about the demand mechanisms participating in this pre-market selection process. In his exhaustive empirical work on the semiconductor industry (Dosi, 1984), the selection mechanisms are centred more on the institutional forces (i.e. military policies) shaping technological trajectories, than on the paradigms. The main purpose of this paper is to extend this conceptualisation (by means of a case study) and to follow Dosi's intention to 'suggest some interacting mechanisms between technological factors and economic factors' (Dosi, 1982: 159). Rather than considering pure demand signals alone as selection devices, we try to show that inducements for technical change cannot be explained merely by economic forces. Dosi frequently adopts the concept of 'focusing device' to characterise the role of demand in the selection process. The term focusing device was coined by Rosenberg (1969: 3) in a seminal article, where he stated that:

Our position is that ultimate incentives are economic in nature, but they are so diffuse they do not explain too much in terms of the particular sequence and timing of innovative activity …. My primary point is that most mechanical productive processes throw off signals of a sort which are both compelling and fairly obvious.

Consequently, we include some endogenous technological signals (namely, the 'technological resistance' of paradigms) interacting with demand forces in this pre-market selection process, to take account of 'the inner dynamics of the engineering dimension of technological paradigms' (Verspagen, 2005: 4). Based on this interaction, we try to explain the 'particular sequence and timing of innovative activity' deriving

from the upstream selection of technological paradigms, for which economic forces alone cannot account.

We want to introduce some broad methodological questions. As stated above, our case study is based on the evolution of the artificial disc. Case study research is one of the most suitable methods for building theories (Ghauri et al., 1995). Our intention is to extend the paradigm selection theory from Dosi's original idea; this process of theory generation will include a description of which variables will be included, and will explore the nature and degree of association between the main variables (Snow and Thomas, 1994). In Section 2 we develop a conceptual framework to serve as a reference for the empirical case. The analysis follows a 'pattern matching' strategy (Yin, 1989): we compare the events that derive from the conceptual framework and the events that are empirically tested. However, the conceptual framework is not based on a purely deductive process; relationships between variables emerge from the empirical analysis, and are compared with the data in a highly iterative process (Eisenhardt, 1989). To give a flavour of this iterative process, we include in the case description (Section 3) some empirical findings that serve to refine some of the definitions of our framework. We discuss the limitations of our study and offer some conclusions in Section 4.

The conceptual framework used in this study has another epistemological mission. As already stated, the aim is to analyse the interactions between the demand and technology variables. Thus, we focus the empirical attention on these two 'realms': the market conditions and the technological projects whose expected outputs are innovative artefacts. For the agency behaviour (i.e. firms' innovative activity) needed to explain

this relationship we use several assumptions based on empirical studies and the results of formal modelling.

Finally, we briefly discuss the choice of paradigm as the unit of analysis for our study. We identify the technological paradigms involved in the solution to a very specific problem: the replacement of a damaged spinal disc with an artificial prosthesis. Some authors (Freeman and Pérez, 1988) have talked about 'techno-economic' paradigms, which affect large areas throughout the economic system, which is the most common understanding of paradigm in the literature. However, Dosi (1988: 225) says that 'a techno-economic paradigm … is a macro-technological concept and refers to broad clusters of "paradigms" in the sense I suggest'. By definition, the technological paradigm is a model solution to selected technological problems. The magnitude of the problem is irrelevant if a coherent design heuristic or research programme can be derived from these paradigms. Recent empirical studies that use the paradigm trajectory framework, such as Dew's (2006) study of wireless bar codes and readers or Castaldi et al.'s (2006) study of the evolution of tanks, employ the artifact as unit of analysis in a similar manner to that adopted in the present study.

2. The conceptual framework

We provide a set of assumptions that will constitute the conceptual framework and help to explain our paradigm selection case: we identify the economic and technological factors (and their relationship), that act as a focusing device upstream in the innovation process.

We begin by looking for the sources of technological paradigms. One of the most important conclusions of Dosi's contribution is that the supply side knowledge base is the source of possible paradigms, defining the range within which inventions can adjust to changing economic conditions. We examine two properties of this knowledge base to analyse the sources of the two paradigms we are studying. First, the localised and cumulative nature of technological innovation (David, 1975; Nelson and Winter, 1982) drives us to search among the technological capabilities possessed by the sectoral knowledge base to find the source of one of these technological paradigms. Second, due to the markedly sector-specific nature of this knowledge-base (Malerba, 2002), we apply Pavitt's sectoral taxonomy of patterns of technical change (Pavitt, 1984; Dosi, 1988) to identify the idiosyncratic sectoral source of the other paradigm in our case study.

We need to establish the position of the 'economic forces' in our framework. The main critics of demand-pull models argue that it is not possible to distinguish between a shift in demand and a technological shift in the supply side that moves the equilibrium point of a static demand curve (Mowery and Rosenberg, 1979). Dosi (1997) highlights the ambiguities in the kind of demand influence in innovation processes.[3] We therefore focus on sales (Cohen, 1995) rather than demand measures to capture the effects of market size and growth which, in a pure demand pull model, trigger technological innovation (Schmookler, 1966; Antonelli, 1998). As we include other technological variables in the model, we do not consider the relationship between sales and some kind of innovative output, but only the direct relationship between sales and firms' research and development (R&D) investment (Jaffe, 1988).

[3] 'Does one talk about observed demand? Expected demand? And how are these expectations formed?' (Dosi, 1997: 1536)

We try to capture the relationship between this R&D investment related to market growth and technological achievement. This relationship will constitute our focussing device in the paradigm selection dynamics. A model developed by Silverberg and Verspagen (2005) formalises this relationship in a clear and intuitive way. Similar to Dosi (1982: 154) ('in terms of our model one can define a technological frontier as a set of points in a multidimensional space'), they stylised a technology space as:

a lattice, unbounded in the vertical dimension, anchored on a baseline, with periodic boundary conditions. The horizontal space represents the universe of technological niches. The technology space is represented as one-dimensional, but it can easily be generalized to higher dimensions or different topologies. The vertical axis measures an indicator of performance intrinsic to that technology …. Each site on the lattice is initialized with a 'resistance' value, which we denote by q_{ij}. When an agent invests 'b' units of R&D with the aim of discovering the site, the resistance value is diminished according to the following process:

(1) $q_{ij,t+1} = q_{ij,t} - b\,\omega$

where ω is a random variable drawn from a uniform distribution on [0, 1], representing the stochastic nature of the R&D process. The subscripts t and t+1 denote the value of the resistance factor before and after the agent's R&D project. (Silverberg and Verspagen, 2005: 4)

More generally (not considering the iterative accumulation of research projects) we will consider $q_{ij} = b\omega$ as the necessary condition for a single research project to become an

innovation. As 'b' in Silverberg and Verspagen's framework is the 'project' investment, our unit of analysis for the technological side is the research projects that try to overcome the technological resistance of paradigm i in its j level of performance.

Having established these conditions in performance and investment, the supply side will decide which paradigm is selected as a heuristic device for its productive activities. We consider that this innovation process cannot be guided by immediate action derived from 'perfect rationality'; it must be conducted by a learning process (Nelson & Winter, 1977). In order to do this, we follow Willinger and Zuscovitch (1993) in distinguishing two phases that precede the paradigmatic phase of a generic technology: the pre-paradigmatic and the self-structuring phases. The first phase is characterised by the emergence of technical solutions which are at the root of the new generic technologies. The second is characterised by the industrial learning of the new technical solutions. In the paradigmatic phase, the model selected is transformed into a production technology in which trajectories can be traced.

To use this learning process as a historical structure for our case narrative, we need to include each of the components of our conceptual framework in some of the stages of the process. Regarding the constitution of the knowledge base that will serve as the source of our paradigms, we include it in the pre-paradigmatic phase; we reflect the 'Dosian' market-independence of this constitution by considering the pre-paradigmatic phase as the stage where technological activity exists, but without sales activity. Then, in the self-structure phase agents will learn - through different development projects - whether the R&D investment provided by sales is enough to overcome the

technological resistance of the paradigms. Once this relationship is known, the supply side will select one paradigm to develop through the paradigmatic phase.

3. The case

3.1 Introduction

Intervertebral disc arthroplasty (the replacement of the articulation of the anatomic disc by an implantable artifact) is a surgical procedure used in the treatment of Degenerative Disc Disease (DDD). DDD is the greatest cause of pain and incapacity in the populations of developed countries (Errico, 2005).

Intervertebral disc arthroplasty has been postulated as being a more efficient alternative treatment for DDD than other surgical procedures, such as vertebral arthrodesis, which since the late 1970s, has been systematically used in the treatment of DDD (Acosta et al., 2005). Arthrodesis consists of the bone fusion of the two vertebrae adjacent to the degenerated disc. Arthrodesis eliminates the abnormal movement of the damaged disc, thus removing the pain this anomalous movement causes. However, fusing two previously articulated vertebrae involves several biomechanical alterations in the behaviour of the vertebral column: (i) the movement of the instrumented articulation must be incorporated into the discs of the adjacent vertebral articulations; (ii) the loads that were absorbed by the now immobilised disc must be absorbed by the discs of the adjacent articulations. These kinematic and dynamic alterations following arthrodesis can provoke 'adjacent disc degeneration syndrome': following fusion, both the excess of movement and load results in the appearance of DDD in the discs adjacent to the fused level, and the need for some kind of surgical intervention frequently occurs

(Denoziere and Ku, 2006). The procedures using an artificial disc try to avoid these problems associated with vertebral fusion.

Looking at the history of artificial discs, one fact in particular stands out. As previously stated, an artificial disc must fulfil two tasks in order to prevent the DDD syndrome of the segments adjacent to the disc that was originally symptomatic: it must not alter the kinematic and dynamic conditions of the anatomic intervertebral discs of these segments. However, as we will see in the following section, the commercially available discs meet only one of these prerequisites: preservation of the kinematic properties of the adjacent discs. None of the artificial discs that have been produced commercially can mimic dynamic properties of the anatomical disc, as they can not absorb loads (Oskouian et al., 2004) since they are all constituted of articulations between materials (polyethylene, Cr-Co, steel…) that have much smaller load absorption capacity than the anatomical disc.

The medical literature has formulated a hypothesis to explain this shortcoming (Bono and Garfin, 2004): designs for vertebral disc articulation were influenced by the enormous efficacy of the implants used to replace hip articulation. In the early 1960s Sir John Charnley designed the hip prosthesis, which some years later would become the standard implant in the treatment of degenerative disease of this articulation. Charnley's hip prosthesis (and succeeding designs) was integrated by two spherical articulation elements (the term used to describe this type of articulation is 'ball-and-socket') made of rigid materials. This rigidity does not imply a functional shortcoming, since the anatomic articulation of the hip does not have the viscoelastic 'shock absorbing' properties of the intervertebral disc.

Hence, transferring the hip prosthesis principles to disc replacement, as in the artificial discs commercialised to date, implies the assumption of an important deficit: if the artificial disc cannot absorb loads, the corresponding overloads will be charged on the adjacent discs at the instrumented level, which can lead to the degeneration of these discs (McNally et al., 1996). This possibility of adjacent degeneration is, in fact, the main reason why arthrodesis (vertebral fusion) is considered to be a suboptimal procedure in the treatment of DDD.

However, in the history of artificial disc design we can find a considerable amount of past and current technological activity in other directions than the hip-like artificial disc, although without the same market success. Szpalski et al. (2002) reviewed not only currently marketed artificial discs, but also several devices only tested in vitro or in animal models, and also some devices that were clinically tested, but never commercialised. They found that there have been many artificial disc designs based on the principles of 'shock absorbing' biomaterials that actually enable the reproduction of viscoelastic properties of the anatomical disc, although they were limited to non-market applications. They concluded that artificial disc designs can be categorised as being based on two principles: these 'shock absorbing' designs or the already described 'hip like' devices commercialised to date. This classification is shared by others reviewers of artificial discs, such as Lee and Goel (2004) and Travis (2007).

We will employ the term 'paradigm' rather than 'principle' to allude to the 'shock absorbing' and the 'hip like' models of solution. In Section 1 we referred to the notion of a paradigm being a model and pattern of solution for selected technological

problems. In this case, one paradigm, the 'hip like' articulation, proposes a solution model to replicate the movements of the anatomical disc based on the kinematics of the rigid solid. Other designs based on the viscoelastic shock absorbing properties of the materials (the non-linear relationship between load and deformation) simply cannot be defined according to these properties. The two fields (the kinematics of the rigid solid and the behaviour of viscoelastic materials) are exclusive: design behaviour will refer to the operational principle of only one of these and never to both. In any event, a classification ruled by this criterion will not be ambiguous, thereby justifying the adoption of these two paradigms as the foundation for this study.

In the next section we look at specific issues in the historical evolution of the artificial disc highlighted by our conceptual framework. As Section 2 showed, the selection dynamics are conditioned by the existence of paradigms capable of being selected, by the technology resistance intrinsic to those paradigms, and by the evolution of sales. In the study of this case dynamics, we first need a brief overview of these phenomena.

3.2 The pre-paradigmatic phase and the source of paradigms

As previously stated, we consider the pre-paradigmatic phase as the stage in the learning process where the technological solutions, which are at the root of future production technologies, emerge. Following Dosi's assumptions, we consider the existence of these solutions independent of market signals, so we study technological activity before any sales were reported. In searching the sources of these pre-paradigmatic activities, we examine two properties of the orthopaedic industry knowledge-base, i.e. its cumulative and sector-specific characteristics.

3.2.1 The shock absorbing paradigm. User's knowledge as source of paradigms

The medical devices industry has often been conceptualised as providing capital inputs for medical services (Pammolli et al., 2005 ; Gelijns et al., 1996). There is also plenty of evidence that medical surgical equipment is an area where the user's innovation is relevant (see, for example, Shaw, 1986; Biemans, 1991, Kahn 1991, Roberts 1988). Therefore, it seems justified to classify this sector, according to Pavitt's (1984) taxonomy, as a typical 'specialised supplier' sector. In these sectors, innovative activities relate mainly to product innovations, which enter other sectors as capital inputs; firms within this classification operate in close contact with users.

Specifically related to medical surgical equipment, recent empirical studies have proved that surgeons are the source of radical new paradigms and influential innovation (Lettl et al., 2006). In medical technology, the users are the professionals; they use the medical technology in their lives, and can apply their 'professional' knowledge to develop innovative solutions. The physical properties of the spine can be regarded as the 'basic science' of orthopaedic spine surgery, as they are the professional knowledge indispensable to interpreting, analysing and, if necessary, correcting abnormal human anatomy and physiology (White and Panjabi, 1978). The 'shock absorbing' properties of the spinal anatomical disc have been known about since 1954, when Hirsch and Nachemson (1954) published the results of compression tests. Nachemson (1962) was the first person to propose replacement of interverbral discs, and reported trials using silicon (a material with 'shock absorbing' properties) prostheses. Urbaniak et al. (1973) produced and successfully tested in chimpanzees several designs approximating the shape of an intervertebral disc, made of a Silicone-Dacron composite, also with 'shock absorbing' properties. No further developments or human clinical trials are recorded in

the literature on this project. In 1977 Fassio and Ginestie (1978) designed an elastic disc replacement using silastic, an inherently compressible material. The device was implanted into three patients, but at four-year follow-up, in every case, the device was found to have migrated into the vertebral body.

Basalla (1988) showed that the source of certain inventions is imitation of natural objects (so-called 'naturfacts'). In the case of prostheses, the artifact conceived to replace functionally a 'naturfact', an organ of the human body, this mimicking driving force is very powerful. This imitative mechanism can be observed in Nachemson's journey from his 1954 description of shock absorbing properties to his 1962 first silicon prosthesis trial. Based on this medical knowledge and these early conceptions of disc replacements, some developers have been trying to preserve the natural flexibility of the spine, according to what we have called the 'shock absorption' paradigm.

3.2.1 The hip like paradigm. Existing capabilities as sources of paradigms

In a recent article, lo Storto (2006) analysed the technological innovation strategy of the European medical prostheses industry, concluding that local search is one of the main options for this industry. Local search occurs when engineers recombine the components of a familiar set of technologies or refine combinations of technologies previously used, exploiting their existing capabilities (March, 1991). Dosi commented that when looking for the source of technological paradigms, we have to take into account that agents will 'seek to improve and to diversify their technology by searching in zones enable them to use and build upon their existing technological base' (Dosi, 1988: 225).

As mentioned above, many of the artificial discs that were developed (and all commercialised to date) 'apply the design principles commonly used in total hip arthroplasty' (Fraser et al., 2004: 245S). These hip design principles are easily identifiable as the local search strategies mentioned above, because the hip-like paradigm for the artificial disc consists basically of recombining the components of hip prostheses and adapting them to spinal anatomy (Santos et al., 2004).

As mentioned in Section 3.1, hip prosthesis in its present form was developed by a British surgeon, Sir John Charnley, in the 1960s. The orthopaedic industry as a whole was marked by the developments in total hip replacement to the point that some reviews of the history of the industry are divided into pre-Charnley and post Charnley eras (Crowninshield, 2000). Orthopaedics is the second largest medical device area after cardiovascular. Although many orthopaedic implants are used in procedures other than the replacement of arthritic joints, joint replacement represents about two-thirds of the total revenues generated by the orthopaedic industry, and it is the leading technology force in the sector (Miller, 2002). Charnley's main contribution consisted of identifying a suitable plastic material (Ultra High Molecular Weight Polyethylene, henceforth UHMWPE) to bear with the spherical metallic component of the femur prostheses. Even more important was the influence of the success of hip replacement in other joint surgery and in the industry in general. Charnley's findings provided the basis for prosthetic replacement of arthritic knees, shoulders and elbows (Crowninshield, 2000). The 'hip like' paradigm allowed the orthopaedic industry in its search for a new joint replacement (the artificial disc) to exploit the bearing materials knowledge developed previously and with great success for other non-shock absorbing joints (Bono and Garfin, 2004).

In 1978 Hoogland et al. (1978) designed and tested in cadaveric human spines a prosthesis composed of a UHMWPE platform and an attached metallic hemispheric articulating surface. No subsequent development was reported; this prosthesis can be considered as the first 'hip like' prosthesis. The first conceptions of the next 'hip like' implant, the SB Charité, date back to 1982. The first human implantation was performed in Charité Hospital (Berlin) in 1984, by Zippel (Bütter-Janz, 2003). This design took the form of two metallic platforms encrusted into the adjacent vertebras, which were articulated with a UHMWPE body. A German company (Waldemar Link), dedicated to the manufacture of hip implants since the late 1960s, was part of the development team. This is an important part of the story: in the mid 1980s, hip joints were already a successful implant with important technological capabilities built around the 'ball-and-socket' paradigm established by Sir John Charnley. Waldemar Link brought its technological experience in hip manufacturing: after some fractures of the prosthesis endplates caused to the material chosen (non-forged stainless steel), a new Co-Cr cast alloy developed for hip prosthesis was selected, and in 1987 SB Charité was for the first time commercially available in Europe, starting the sales register for artificial discs and ending what we are considering the pre-paradigmatic phase of artificial disc evolution.

3.3 Selection dynamics: self structuring and paradigmatic phases

Having established the source of the paradigms and their emergence through the pre-paradigmatic phase, we turn to our main objective: explaining the supply side selection of paradigms through the interaction of economic and technological factors acting as a focusing device This selection occurs after a self-structuring phase, in which an industry

learning process will 'discover' whether the R&D investment derived from sales conditions is enough to exceed the technological resistance of the paradigms. We show how this learning is achieved through various development projects, and which results will show the success or failure of R&D investments. To study these dynamics we describe: (i) sales evolution; and (ii) the technological resistance intrinsic to paradigms.

3.3.1 Sales evolution

SB Charité was the only artificial disc available from 1987 until another 'hip like' device, ProDisc, came on the market in 1999 and was available in most countries except the USA. Between then and 2006, eight other artificial discs were available in world markets other than the USA (Engelhardt, 2006b) and in 2004 SB Charité was approved for use in the USA (Food and Drug Administration, 2004). It is important to remember that all the units sold belong to the 'hip like' paradigm, as to date there are no 'shock absorbing' projects which have advanced to the innovation phase and been commercialised. This circumstance avoids the hypothetic effect in the resultant dynamics of different sales composition throughout time. We have information on sales for the period 2000 to 2004, collected by Biondo and Lown (2004), which shows the growing commercial worldwide implantation of artificial discs from 2000 (356 devices implanted) to 2004 (11 600 devices implanted), with a median of 4.883 implants per year in that period. SB Charité were used since 1987, with a total of 5 000 devices implanted by October 2002 (Guyer and Blumenthal, 2003). Biondo and Lown provide data showing that 1 700 SB Charité discs were implanted in the 2000-2002 period (300 in 2000, 600 in 2001 and 800 in 2002), so we can assume 3 300 artificial discs implanted for the 1987-1999 period (as SB Charité was the only commercial disc available at that time) and a median of 250 devices per year implanted before 2000,

which gives a notion of the acceleration artificial discs sales in the 2000-2004 period (Figure 1 and Table 1).

- Insert Figure 1 about here-

- Insert Table 1 about here-

It is not the objective of this paper to go into the reasons for this sales evolution; here, we are mainly interested in the role of this evolution as part of the focusing device for paradigm selection. However, it might be useful to understand (in a somewhat impressionistic way) the whole framework. We can use as a comparison the study by Metcalfe et al. (2005) which examined another type of medical device: the intraocular lens. Metcalfe and colleagues found four reasons for the rapid growth of the market for these lenses in the 1970s: the extension of the regulatory regime, the ageing population structure, the development of a supply capability and the growth of clinical and medical knowledge of the technique. We can find four similar reasons for the growth in artificial disc sales.

The FDA approval process of SB Charité began in 2000 - when the application for an Investigational Device Exemption (IDE) study was made – and went on to 2004, when the results of this IDE study allowed FDA to approve the use of the artificial disc in the USA. This 2000-2004 period coincides with the sales acceleration depicted in Figure 1, so we will use the FDA approval application as a mark of sales condition. The North American market represents more than two-thirds of the world market for spine implants (Weinstein et al., 2003), but has the most restrictive regulations regarding the commercialisation of surgical implants, in that the IDE tests, in terms of methodology and procedure, are highly demanding. Given the historical market trend for accepting

new technology in spinal surgery, the estimates of market growth were projected to reach $2.18 billion and 47.9% of market share for DDD pathologies within five years of release; these estimates increased the popularity of the technique for surgeons outside the USA and stimulated the development of new devices following the SB Charité application for FDA approval in 2000 (Singh et al., 2004).

Another reason for the growth in the artificial disc market was the development of clinical knowledge within the community of surgeons. This knowledge, which heavily depends on practice, is represented by published papers, and trends broadly reflect actual hospital and clinical practice (Metcalfe et al., 2005). We examined the scientific papers listed in Medline between 1962 (the year of Nachemson's report on the first trial of an artificial disc) and 2005, and found an acceleration trend (Figure 2) similar to that depicted in Figure 1.

- Insert Figure 2 about here-

The development of supply capabilities also resulted in growth in the 1962-2005 period. In 1962 the Harrington system for scoliosis correction was the first specific implant for spinal surgery introduced in the market (Biondo and Lown, 2004). Due to the limited prevalence of scoliosis disease the proportion of procedures was very small compared to other orthopaedic areas, and therefore there was not a similar supply capability. This trend began to change in the mid 1980s, when some procedures (originally developed to treat deformities) were applied to degenerative diseases of the spine, involving extraction of the painful part and establishing the segment with screws, bars and plates. The total spinal market grew from $6 million in 1980 to $60 million in 1989 (Fridth, 2003). In the mid 1990s, the use of the devices invented in the 1980s for degenerative

disease begin to be established as normal procedures in orthopaedic surgery and other kinds of devices were developed to improve fusion between vertebrae. This made the spinal market the fastest growing sector in orthopaedics from 1995 (Deyo et al., 2004), with total revenues in 2003 of $2840 million and a yearly growth of 19.8% (Knowledge Enterprises, 2004).

Apart from these industry specific causes, we can find other more general reasons for artificial disc sales. Part of the recent growth in the spinal market is frequently attributed to the expansion in patient populations; the baby boomers expect to be active longer and, with the prevalence of spinal pathology, they will demand more effective and expeditious spinal care (Standard and Poor's, 2004).

3.3.2 Technological resistance

As Section 2 showed, our model of technology implies that when q_{ij} resistance is exceeded by R&D investment b_m, the technological paradigm j can achieve i level of performance, say p_{ij}. For example, we can consider that when the q_{11} resistance of the hip like paradigm (noted here as j=1) is exceeded, the resultant devices can achieve a specific level (i=1) of performance p_{11}. As we have seen, this kind of 'hip like' implant can only mimic the kinematic properties of an anatomical disc, as the rigidity of materials necessary for the design solutions of this paradigm cannot reproduce the shock absorbing properties of the natural structure. If we consider p_{12} as the level of performance of an artificial disc that includes not only kinematic, but also shock absorbing properties, q_{12} has to be infinite to assure p_{12} cannot be achieved, as no R&D investment can solve the inner contradiction of trying to mimic a 'perfect rigid solid'

movement of sliding, and at the same time absorbing loads, as these materials are not viscoelastic.

This has important implications for our study, as it means technological paradigms are difficult to compare in terms of performance (Dosi, 1982: 154). This can be caused by the quantum nature of technological innovation (Silverberg, 2002), reflected, for example, in our concept of 'technological resistance', which implies that innovation only 'jumps' when a discrete resistance is exceeded. In the same manner this 'discrete' resistance to achievement is intrinsic to each paradigm, the 'discrete' performance of each paradigmatic achievement can 'jump' on a different scale for different paradigms (Frenken and Leydesdorff, 2000).

The same situation arises if we consider the 'shock absorbing' paradigm (noted here as j=2) and p_{21} the performance, which implies that only the kinematic properties of anatomical disc are mimicked and not the shock absorbing properties; it is obvious that an artefact designed by a 'shock absorbing' model of solution cannot function in this way. However, p_{22} can be achieved by the 'shock absorbing' paradigm, if it mimics the dynamic properties of the anatomical disc. In this case, q_{22} could be exceeded by enough investment in R&D, achieving this p_{22} level of performance. Thus, each paradigm has its own q_{ij} and p_{ij} scaling depending on its intrinsic technological characteristics.

3.3.3 *Selection dynamics*

1987-1999 Pre-FDA SB Charité approval application: With these intrinsic technological conditions established, we can now trace the selection dynamics as the evolution of sales occurs. We begin with the sales condition in the pre-FDA approval period (1987-1999). This was the self-structuring phase, where agents were trying to establish whether the investment derived from this first sales condition would be

enough to exceed the technological resistance of the paradigms. We found details in the literature of four 'shock absorbing' projects launched in this phase. In 1993, Enker et al. (1993) reported first experiences with a new elastic disc implant: the 'Acroflex' artificial disc, which consisted of a rubber core interposed between porous, coated titanium endplates. Three different series of designs were conceived and tested in three sets of clinical trials as part of a considerable research effort that began in 1988. In spite of this development effort, it was not possible to avoid mechanical failure of the rubber (Fraser et al., 2004). In 1991 Hedman et al. (1991) published an article presenting criteria for the design of a new intervertebral disc. This implant was made of two titanium springs between cobalt-chrome hinged alloy plates screwed to the vertebral bodies. Although it performed well in in vitro testing, the device failed in animal implantation, with springs tending to break after long periods of use (Kostiuk, 1997). Langrana et al. (1994) developed a composite implant constituted of an elastomer and a fibre reinforcement structure. They tested the influence of the orientation of layers, the number of fibre layers and the order of the reinforcing layers and concluded that although the design rationale was sound and the test results encouraging, reproducibility could not be ensured in the manufacturing process. Finally, Vuono-Hawkins et al. (1995) developed a design of 'multidurometer' elastomeric materials, i.e. an implant constituted of different elastomers with different elastic modulus, mimicking the anisotropic properties of anatomical discs. The test results showed device behaviour comparable to the intact spine. No further research was found about this project in this period.

Contrasting with the failed or abandoned 'shock absorbing' projects, 'hip like' projects launched in this period ended in the commercial introduction of the devices. Thierry

Marnay, a French surgeon, designed an artificial disc which consisted (as did SB Charité) of three pieces, two metallic platforms and a central polyethylene core However, in contrast with SB Charité's two bearing surfaces, in Prodisc (the brandname of this new disc) the polyethylene core was fixed to the inferior end plate, so a single polyethylene-Cr-Co bearing surface acted as the artificial joint (Marnay, 2004). The final implant design and instrumentation was completed at the end of 1989, and the first clinical study started at the beginning of 1990 (Tropiano et al., 2003). In 1999 the results from the first study proved acceptable, and Prodisc received the CE mark and began to be commercialised outside the USA.

Chronologically, the next project was in 1990, when Cummins et al. (1998) started the design of a two piece disc joint, the 'Prestige' prostheses: for the first time the polyethylene core was abandoned and the bearing was performed between the surfaces of two stainless steel platforms, anchored to adjacent vertebrae with anterior screws. Clinical trials were initiated in 1991 and when results proved acceptable Prestige went on the market in Europe.

Like the ProDisc and SB Charité, the Bryan Disc, developed by Dr Vincent Bryan, also has a plastic articulating core, but it features a flexible polyurethane membrane that spans the metallic end plates to seal the articulating surfaces from the surrounding tissues. Saline 'joint fluid' contained inside the membrane serves as a lubricant (Santos et al., 2004). The project began in 1993, when Dr Bryan 'did the drawings for the device' (Mitulescu, 2002: 7). Rigorous preclinical trials were conducted in a variety of models, including bench-top mechanical testing, cadaveric experiments, and a unique

chimpanzee survival study. After this extensive R&D, the first Bryan Cervical Disc was implanted in Leuven, Belgium, in January 2000.

Based on our assumptions and the empirical data, we can conclude that sales conditions in this phase provided enough quantity of R&D investment (b_1) to exceed the technological resistance of the hip like paradigm, as evidenced by the successful projects that began in the first part of the 1990s. The trial and error process culminated in commercial products for all three 'hip like' projects whereas the difficulties encountered in the 'shock absorbing' paradigm could not be overcome by this investment. One important observation is that there are no registers for 'shock absorbing projects' beginning in the second part of the 1990s, reflecting the learning of the four projects abandoned or failed in the 1987-1994 period.

2000-2006 Post-FDA SB Charité approval application: In this context, our model predicts that a 'hip like' paradigmatic phase will follow, as a result of the learning process which demonstrated that the R&D investment was not enough for the 'shock absorbing' projects that were abandoned in the second half of the 1990s. But the change in sales conditions in the post-FDA application phase implied another different b_2 quantity of R&D investment. Here, the beginning of a second self-structured phase of paradigm construction is tied to the specific characteristics of the technology. As we have seen, there is no investment that can exceed the infinite q_{12} technology resistance for the 'shock absorbing' properties of the 'hip like' paradigm, as there is no intrinsic technological possibility to achieve those properties with the model of solution given by the 'hip like' design heuristics. So, there cannot be a new self-structuring phase for the

'hip like' paradigm, which, in contrast, will follow a paradigmatic trajectory based on the successful projects of the pre-FDA phase.

In contrast, the new post-FDA application sales conditions imply that the supply side needed to know whether the new investment conditions b_2 could exceed the q_{22} technological resistance of the 'shock absorbing' paradigm (which could not have been exceeded by the b_1 investment of the pre-FDA sales conditions). So our 'pattern matching method' predicts that new 'shock absorbing' projects will be launched to estimate the new situation.

We have information from three industry reports (Engelhardt, 2004a, 2004b, 2006a) about artificial disc projects launched or developed in the 2000-2006 period. According to Kleinknecht et al. (1993), innovative activity can be identified from articles in specialist journals if these publications have a section on innovation and only information appearing on this section is analysed (advertisements are ignored); also if press releases are included they must provide information on the technical characteristics of the innovation. Applying this methodology and conditions, we identified 19 research projects in the period studied which we classified in our paradigm framework based on their technical details. There are 11 hip-like projects, corresponding to the paradigmatic development of the paradigm. We can identify eight so-called 'sons of Acroflex' (Engelhardt, 2004b, referring to the long 'shock absorbing' failed project of the 1990s referred to above), that is, the new 'shock absorbing' projects resulting from the new b_2 investment conditions of the post-FDA sales phase. Table 2 summarises these and past empirical data in terms of our framework, and can be considered as the main empirical results of this study.

-Insert Table 2 about here-

4. Conclusions and limitations of the study

Our main results describe the relationship between sales, R&D investment and the intrinsic technological resistance of technological paradigms. In our case, changes in sales conditions led to the investment reconsideration of technological paradigms that had been abandoned because of the excessive effort needed to exceed the intrinsic technological resistance under the previous sales conditions. From an evolutionary perspective, these changes in sales conditions affect the pre-market selection process of paradigms by the supply side. The study of these 'internal' selection processes is an important issue in evolutionary economics, as they are relevant processes which have to be reconciled with selection in competitive markets (Knudsen, 2002). This paper is an attempt in that direction, based on the study of the technological evolution of the artificial disc.

The relationship described extends Dosi's original theory on the role of demand in the upstream selection of technological paradigms. Although Dosi claimed that the role of demand 'does not imply by any means an assumption of malleable "ready-to-use" alternative technological paths' (Dosi, 1984: 35), we believe that an explicit link with technological variables is needed if technological choices are not to be regarded as reactive adjustments to the pressures and signals of economic forces, as the neoclassical theory of technological change claims (Frenken, 2006). We have added to these economic considerations some technological considerations which help to explain the historical supply side choices in the evolution of the artificial disc. We structured this

empirical work within a conceptual framework that includes (apart from the relationship between sales, investment and technological resistance mentioned above) the sources of paradigms and the learning process needed to materialise the selection dynamic.

One of the main limitations of this research is that we have to consider the technology 'stable' in all the period studied. Our assumption is that the 'pieces of technological knowledge' (Dosi, 1982: 151) were already there in those 20 years, and all that was required was enough R&D investment to 'assemble' them to arrive at a paradigmatic phase. A deep technological study would be required to demonstrate that it was not the push of new 'shock absorbing' scientific principles (referred to, for example, in new biomaterials) that created the 'sons of Acroflex' generation of 'shock absorbing' discs in the post-FDA application sales phase.

Although such a study is beyond the scope of this article, we can trace the evolution of a specific case of a 'shock absorbing' project that shows behaviour consistent with our 'technological stasis' assumption. We referred in Section 3.3.3 to Vuono-Hawkins et al.'s (1995) project of a 'multidurometer' artificial disc, constituted by different elastomers with different elastic modulus, mimicking the anisotropic properties of anatomical disc. The biomechanical tests showed good results, but no further animal or clinical research was undertaken. However, in 2004 some of the researchers involved in this project formed 'Nexgen Spine', a company devoted to the development of artificial disc prostheses. As explicitly stated in the 'short history"' provided on its webpage (http://www.nexgenspine.com/History.htm), the products developed by this company are based on the evolution of a 1982 patent described in the 1995 article. No post-1995 patents or articles are mentioned as part of the knowledge base of the currently

developed artificial disc, so at least in this specific case it seems that this 'son of Acroflex' was relaunched because of the new investment conditions of the post-FDA era, which is in line with our assumptions.

These and other empirical issues reflect the embryonic stage of our conceptualisation. Further research is needed to extend the conclusions of this single case study.

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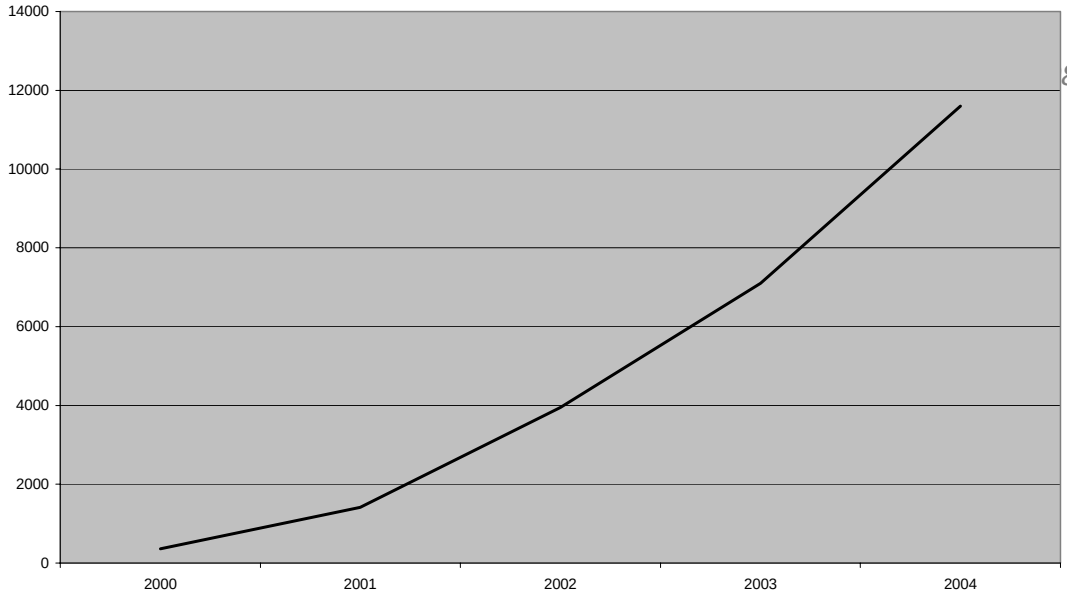

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Figure 1. Artificial discs commercially implanted, 2000-2004.

Years	Implants sold	Implants sold/year
1987-1999 (Pre-FDA approval application)	3 300	275
2000-2004 (Post-FDA approval application)	24 416	4 885

Table 1. Implants sold during the Pre-FDA and Post-FDA approval application periods.

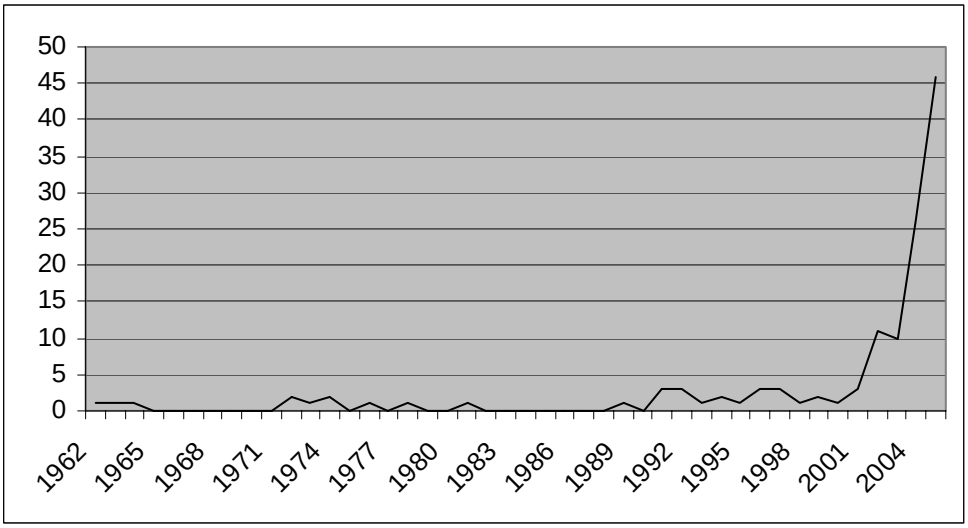

Figure 2. Scientific articles about artificial disc, 1962-2005.

Phases	**Sales condition**	**Number of 'Hip like' projects**	**Phases**	**Sales condition**	**Number of 'Shock absorbing' projects**
1972-1987 Preparadigmatic	No sales	2	1972-1987 Preparadigmatic	No sales	4
1987-2000 Self-structuring	Pre-FDA	4 ($q_{11}<b_1.w$) *Succeeded and commercialised*	1987-1994 Self-structuring	Pre-FDA	4 ($q_{22} > b_1.w$) *Failed or abandoned ('Acroflex')*
			1994-2000 Non-selected	Pre-FDA	0
2000-2006 Paradigmatic	Post-FDA	11	2000-2006 Self-structuring	Post-FDA	8 ($q_{22} < b_2.w$?) *('sons of Acroflex')*

Table 2. Number of 'hip like' and 'shock absorbing' projects through the stages of the learning process.