

Mapping the Importance of the Real World: The Validity of Connectivity Analysis of Patent Citations Networks.

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Abstract: Recent empirical findings have questioned the use of patent citations as a measure. This points to the need of validation of patent citations methodologies, which we address by testing a recent methodology for studying technological evolution, namely connectivity analysis of citation networks. We find connectivity analysis to be a valid tool to identify the reliable knowledge which opens the way to further technological evolution of a surgical prosthesis, the artificial spinal disc. We also illustrate how connectivity analysis represents how this reliable knowledge differs depending on the stage of technological evolution. The corroborated validity of connectivity analysis of patent citations may trigger a renaissance in the use of this kind of patent data.

Keywords: patent citations; technological evolution; connectivity analysis; validity; medical innovation.

1. INTRODUCTION.

Patents are one of the main indicators used in Innovation Studies, but they present a fundamental problem for the study of technological evolution. One of the essential dimensions of technological evolution is application and use. As Walter Vincenti (2000: 174) states ‘any complete model of technological evolution must include the physical real world. Artifacts, by definition, are made to ‘work’ (in some sense) in the world around them’. But many patents are never applied for nor used in the ‘physical real world’. Some patented projects are rejected because they are not sufficiently profitable (given the firm’s opportunity cost) to warrant development or licensee search (Palomeras, 2003). In other cases, patents are used for strategic objectives: to block rivals and to avoid being blocked, or to improve negotiating power in cross-licensing agreements (Hall and Ziedonis, 2001; Ziedonis, 2004). For example, Giuri et al. (2007) found that more than one third of European patents granted are never exploited. Thus, these patents cannot encompass the ‘real world’ experience, necessary to build a complete model of technological evolution.

Patent citations help to gauge the importance of different patents in technological evolution (Trajtenberg, 1990). Moreover, a recent patent citations methodology - connectivity analysis of patent citation networks- proposes using citations to produce a *sequence* of patents with which to trace technological evolution (Mina et al., 2007; Verspagen, 2007; Fontana et al., 2009; Martinelli, 2008; Batagelj, 2003). Prior to this, a few scientometric studies analysing networks of citations of scientific articles had employed connectivity as their methodology (Hummon and Doreian, 1989).

However, the validity of connectivity analysis, like all patent citation methodologies, is reduced by certain requirements of the legal system, for example, patent examiners' citation additions (Alcacer and Gittelman, 2004, 2006). Alcacer and Gittelman (2004: 26) point out that in using patent citations as a measure: 'the strongest assumption, namely that a citation from patent A to patent B indicates that A used B to invent A, is clearly the most prone to error'. This caveat points to the importance of *external* validation of patent citation methodologies. In the present study we use the terms 'internal validation' and 'external validation' following Jaffe and Trajtenberg's definitions (2002: 9).

By 'internal' validation of patent-based measures we mean the attempt to substantiate the hypothesized role of patent and citation-based measures as indicators of technological impact by examining patterns and relationships wholly within the patent data themselves. By contrast, 'external' validation substantiates the meaning of patent-related data by correlating patent-based measures with independent technological or economic indicators whose meaning is more self-evident.

We believe *external* validation makes 'the results compelling in a way that is much harder to achieve using just internal validation methods' (Jaffe and Trajtenberg, 2002: 10).

Connectivity analysis of patent networks has been applied to the study of technical systems that move between different levels of aggregation (Verspagen, 2007; Fontana et al., 2009; Martinelli, 2008), and to examine the sequence of different product innovations for the treatment of a medical disease (Mina et al., 2007). However, to our knowledge, the present study is the first application of connectivity analysis to a single

product: the artificial intervertebral disc, a surgical prosthesis. This reduced technological scale allow us to undertake a micro-historical¹ study of some of the patents selected by our connectivity analysis of the artificial disc to externally validate this recently proposed methodology. Works on connectivity analysis deal with two dimensions of technological evolution²: the epistemological, which is related to the characteristics of technological knowledge; and the socioeconomic, which is concerned more with the co-evolution of institutions and technology and with organizational strategies. Although both streams are of great interest, we focus on the epistemological dimension in order to concentrate our efforts for a much needed external validation. Concerning this technological knowledge dimension, none of these previous works can provide a *systematic* external validation of the results of connectivity analysis - probably due to the big scale of the problems they address- as they just provide as external data a broad description of the history of the technology treated. Verspagen (2007:94) gives a “brief primer in the technological history of fuel cells”; Fontana et al. (2009:313) provides a “short history and an overview of the evolution of the Ethernet standard base”, Martinelli (2008:1) “sum the main technological ... changes of the telecommunication switching industry”; and Mina et al. (2007:794) give “a brief overview of the problem of coronary artery disease”. Thus, the main contribution of this paper is that we provide the first systematic external validation of the knowledge dimension of technological evolution as depicted by connectivity analysis. On the conceptual side, we will also show how connectivity analysis helps to represent how this knowledge differs depending on the stage of technological evolution.

¹ We use this term from social history, to acknowledge the reduced scale of our historical study (Revel, 1996).

² We thank an anonymous referee for pointing this out.

2. THEORETICAL FRAMEWORK.

2.1 Patent Citations and Technological Evolution

Patent citations can be interpreted in an economic or a purely technological sense (Trajtenberg, 1990; Harhoff et al., 1999; Wartburg et al., 2005). The *economic* value of citations is measurable by the impact of a patent on performance measures. For firms, empirical studies reveal a positive relationship between the number of times that a patent is cited, and firm performance or stock market valuation; however, a recent work by Gambardella et al. (2008) have questioned convincingly the use of patent citations as a measurement of economic value. *Technological* importance can also be approximated by the number of times a patent is cited, and refers to the impact of the knowledge embodied in the patent in terms of stimulating new contributions. In this paper the focus is on this latter technological meaning of patent citations. For us, ‘a patent would be regarded as important if it opened the way to a successful line of further innovation’ (Trajtenberg, 1990: 184). Citations are one way to identify such patents.

But what kind of technological knowledge opens the way to further evolution? Our answer is based on some of the properties of technological knowledge: we believe that inventors that cite other patents in their patent applications are deeply interested in the knowledge deriving from the physical interaction between the ‘real world’ and the patented product where the knowledge embedded in the patent has been used for the development of a commercial product. In our view, the fundamental question about technology – ‘Does it (or is it likely to) work?’ (Vincenti, 1990: 224)- can be answered in large part by the knowledge content of such ‘real world’ patents, that is, those that result in a practical product that is in use. These patents represent the ‘well-corroborated or strongly confirmed knowledge’ that provides a powerful guide for successive

innovations (Constant, 2000: 232). The knowledge content of these ‘real world’ patents acts as an ‘auto-catalyst’ (Metcalf, 2002; Metcalfe et al., 2005) to the growth of subsequent knowledge, thereby enhancing technological evolution. The process of knowledge accumulation departs from these reliable patents, conforming sequences or trajectories of improvements and even new foci for inventive effort (Mina et al., 2007).

Although this is a general claim for technological knowledge, in medical technologies this ‘knowledge that works’ is especially important for technological evolution. As Metcalfe et al. (2005: 1284) point out in their study of the evolution of intra-ocular lenses: ‘applications to the human body are a matter of engineering not of science; as with all engineering innovations, feedback from practical application is the essence of the development of reliable knowledge’. This practical application resides in the clinical use of the medical technology (Gelijns and Rosenberg, 1994). The clinical knowledge is significant because the interactions between artifacts and the human body are so complex that they cannot be fully predicted *ex ante* (Gelijns et al., 1998). In many cases, this clinical knowledge is the true source of innovation in medical technologies (Von Hippel, 1988).

In our case, we use patent citations to study the technological evolution of the artificial disc –a surgical prosthesis used to treat spinal pain-, and the fundamental assumption is that this ‘reliable knowledge’ (Constant, 2002) is represented by patented artifacts which have been used clinically. We try to validate whether the sequence of the patents mapped by connectivity analysis of patent citations is based in this reliable knowledge. If our results prove coherent with this assumption, we will have contributed by advancing external validation of this new patent citation methodology.

In our study we pay great attention to what we call the ‘physical real world’. This is not to neglect the important role of social constructivism in building the selection criteria for inventions to become innovations,³ (Bijker et al., 1987). In fact, the clinical interaction between configuration of the artifact and the human body has to be approved by the relevant institutions such as the Food and Drug Administration (FDA) in the US, and the Notified Bodies of the European Commission in Europe. The FDA gives approval only when it considers that the ‘safety’ and the ‘efficacy’ of the devices being considered has been proven. The European Commission bodies are concerned only with ‘safety’. Proof of the relevance of institutions in building the selection criteria is expressed in this difference, cited as the reason for the ‘slowdown of translation of those technologies into treatments’ in the USA compared to Europe (Miller, 2004: 2).

But, even though socially constructed, our point is that institutionally sanctioned safety and/or efficacy of the knowledge signalled by these artifacts are the main pillar of reliable knowledge. We rely on the fact that if an implant is being used clinically, this implies that its physical configuration has passed all the tests and it has completed all the trials required by the health authorities for it to be classified as a marketable product. These selection criteria assure (at least for the FDA and the European Commission) the efficacy and/or safety of the particular artificial disc designs.

2.2 Connectivity analysis of patent citation networks.

³ I.e., to emerge from the techno-scientific sphere to the market.

Connectivity analysis constitutes a set of tools for analysing patent citations. Hummon and Doreian (1989) proposed the first connectivity algorithm.⁴ They assigned a weight to each citation link on the basis of its position in the overall network structure. The method is based on the examination of the different ‘search paths’ in the network. Search paths are sequences of links that connect the network vertices. In Figure 1, patent A is cited by patent C, which in its turn is cited by patent D. A search path is represented by the sequence A-C-D-F-H-J, which indicates the flow of knowledge from patent A to patent J through several intermediate patents.

- Figure 1 around here.

Hummon and Doreian proposed several connectivity measures. The most used is SPNP (Search Path Node Pair). Consider⁵ the edge C-D (Figure 1). This edge connects three vertices (A, B, C) to the destination (D). At the same time, this edge connects its origin (C) to seven other vertices (D, E, F, G, H, I and J). The SPNP value is the product of these values ($3 \times 7 = 21$), because it connects a total of 21 distinct pairs of vertices. The logic underlying this measure is that the citation links responsible for connecting higher numbers of patents contain the most significant knowledge flows in the citation network.

Based on the work of Hummon and Doreian, Verspagen (2007) added two new algorithms to the connectivity analysis toolbox. The first is the ‘top path’, that is, the

⁴ Hummon and Doreian (1989) used scientific articles citations, but the methodology is the same both for patents and articles.

⁵ This description of SPNP is built on Fontana et al. (2009).

sequence of patent citations from a start point to an end point, whose sum of SPNP value is the highest. The second is the network of the evolution of top paths (NETP). The NETP is constructed by joining the top paths of different temporal intervals. For example, there is a top path for a sample of patents in the period (t, T) . Then add the patents published in $(T, T+1)$. If the (t, T) patents of the $(t, T+1)$ top path are different to any patent of the (t, T) top path, then the latter are no longer part of the top path, but they continue to be part of the NETP since they were top paths in the past. These patents can be seen as ‘dead ends’ where the technology cannot continue to develop (Martinelli, 2008, Verspagen, 2007).

2.3 The importance of the top path and the strategic patents

Patents do not necessarily signal innovations, as some of them are never applied on to the market, but remain as inventions. In this context invention can be understood in two ways (Arthur, 2007): invention as a mere improvement to an existing product (more generally, an existing technology); and invention in the form of a process which brings about a new product or ‘entities that depart in some sense from what went before’ (Arthur, 2007: 274). We will refer to them respectively as Invention 2 and Invention 1. The interactions between the market and the invention process differ substantially for these two different types. When the product to which improvements are being made by an invention is already on the market (Invention 2), inventors receive a ‘special important feedback’ (Kline and Rosenberg, 1986: 290) from the ‘real world’ experience of commercial use. This is especially true for medical technologies, where – as we have seen - regular clinical use is a powerful force driving knowledge growth. Prior to the first introduction of a product to the clinical market (Invention 1) the clinical knowledge

is less accurate, as it is based on old products which are qualitatively different from the new innovation (Schumpeter, 1934; Saviotti, 1996).

On the other hand, there is general agreement about the importance of the top path, which represents ‘the fundamental flow of knowledge (or technological trajectory) in the overall network of patent citations’ (Fontana et al., 2009: 321). Similarly, (Martinelli, 2008: 9) states that ‘the top-path is the critical backbone of knowledge flow’, because according to (Mina et al., 2007: 800), it ‘summarizes the main technological trajectory’. However, what this means in empirical terms is not completely clear. Based on our theoretical argument, we would attribute this to the ‘reliable knowledge’ content in top path patents. But this knowledge will differ depending on the stage of the invention-innovation dynamics represented by the top path. After the first innovation (in Invention 2), the reliable knowledge we search for exists in the sphere of commercial use and, therefore is represented by patented artifacts which have informed associated, real world products in use. Therefore, we would expect that the top path patents identified by connectivity analysis would show high levels of ‘innovative effectiveness’, that is, a high proportion of patents which have been transformed from inventions into commercial innovations.

But in Invention 1 (before the first innovation), the reliable knowledge does not exist in the form of innovation effectiveness, since, by definition, there are no innovations in the market. Thus, for Invention 1 top path patents, the reliable knowledge must be gained through testing the performance of the product during its development (Vincenti, 2000). In the case of surgical prostheses, health authorities require the devices to pass several tests (in synthetic or animal models) and human clinical trials before allowing them to

become commercialized products. The broader sphere of users includes ‘vicarious⁶ users’, that is, the testing engineers who are interested in whether it ‘will work’ in a man-made real world (i.e., the test laboratory), where they conduct R&D on the product. For Invention 1 top path patents we need to search for the reliable knowledge developed by these vicarious users. If our results are coherent for both stages of invention, we will have advanced the knowledge on external validation using this new patent citation methodology.

In terms of the NETP, there is also a ‘structural’ argument related to the relevance of the divergent network junctions, that is, ‘strategic patents’ (Fontana et al., 2009) where two or more patent branches diverge. The literatures coincide in their understanding of divergent junctions as *transitions* from one technological regime to other. For example, in Fontana (2009: 331) a divergent junction signals the transition from invention in a particular device to invention in the overall technical system being studied. Martinelli (2008: 12) interprets the strategic divergent patent as a ‘transition from a creative accumulation to a creative destruction regime’ while Verspagen’s (2007: 12) understanding is that the divergent patent marks a transition from exploration to accumulation and persistence in the evolution of technological knowledge.

Elaborating on the notions introduced before, we consider divergent junctions as transitions from Invention 1 to Invention 2. These strategic divergent patents mark the switch in the invention-innovation dynamics, from the stage where reliable knowledge

⁶We use the term ‘vicarious’ in the sense of ‘vicarious selection’ in the context of cultural evolution (Campbell, 1974). Vicarious selectors function as ‘short-cuts’, or heuristics, in a process of variation and selection, in which one set of criteria substitutes ‘vicariously’ for another, more direct form of selection (Allchin, 1999).

is built in the development of the product by vicarious users (Invention 1) to the stage where the reliable knowledge comes from the commercial use (Invention 2).

3. THE CASE OF THE ARTIFICIAL DISC

The illness we are interested in is the pain related to spinal disorders. In the US this condition is the main cause of pain and disability. In the 1990s, health costs in the US associated with this complaint accounted for an average yearly spend of \$34,000 million, not including the \$16,000 million from productivity losses (Errico, 2005). Spinal pain is attributed most commonly to Degenerative Disc Disease (DDD), which includes the natural ageing processes related to the discs forming the vertebral column. Surgical treatment of DDD consists of the extraction of the diseased and painful disc. Since the 1980s, two alternative operational principles are possible (Acosta et al., 2005): arthroplasty, or the substitution of the articulation of the anatomical disc with an implantable artifact; and arthrodesis or osseous fusion, which is the extraction of the diseased disc and its replacement with an osseous bridge created between the two adjacent vertebrae. Arthrodesis has been widely used in Europe since 1980s, and in the US since the mid 1990s. However, arthroplasty was seen as an almost experimental treatment until quite recently.

The implications of these two treatments are a source of uncertainty. Advocates of arthroplasty claim that fusing vertebrae that previously were articulated implies diverse biomechanical alterations to the behaviour of the vertebral column. For example, the movement of the fused articulations must be absorbed by the adjacent disc articulations,

which therefore are forced to carry a wider range of movement, which could lead to degeneration in these discs (the so-called ‘adjacent disc degeneration syndrome’) and the need for more surgical intervention (Denoziere and Ku, 2006). Procedures that use artificial discs are aimed at preventing the problems associated with vertebral fusion (Figure 2).

- Insert Figure 2 around here-

However, there is significant uncertainty about the relationship between fusion, arthroplasty and adjacent disc degeneration. Two systematic literature reviews confirm that in cases where arthroplasty is used there is no proof that adjacent disc degeneration will not occur (Kleuver et al., 2003; Freeman and Davenport, 2006). This is due in part to another uncertainty: it is extremely difficult to make a causal link between fusion and adjacent degeneration given that such degeneration could be due to the normal progress of degenerative disease in the other discs in the vertebral column (Freeman and Davenport, 2006). On the other hand, some authors, such as Lee and Langrana (2004: 175S), believe that there is sufficient evidence to demonstrate ‘the adverse effects of vertebral fusion on the adjacent segments’.

At the level of arthroplasty, we study the two operational principles proposed for replacement of the anatomical disc with a disc prosthesis. The first operational principle to reach the sphere of clinical use is the operational principle which we refer to as ‘hip-like’. This operational principle is based on the design developed by Sir John Charnley in the 1960s for hip prostheses (Büttner-Janzen, 2003). The discs have rigid contact surfaces and are made of similar materials to hip prostheses, i.e. metal or relatively rigid

plastic, such as the UHMWPE (Figure 3). The SB Charité hip-like artificial disc was the first artificial disc to be commercialized, in 1989.

- Insert Figure 3 around here-

The alternative operational principle, which we call ‘mimetic’, began to be used in normal clinical practice in Europe only in 2007, although the first patents were issued in 1973 and preceded those for hip-like discs.⁷ Although mimetic discs had persistently failed to reach the sphere of use, between 1973 and 2007 numerous R&D projects were dedicated to the development of discs based on this operational principle (Szpalski et al., 2002; O’Reilly, 2008). The mimetic principle is based on the attempt to reproduce the mechanical properties of the anatomical disc, which has different characteristics to those of the hip. The hip is a synovial joint, whose movement is governed by the form of the contact surfaces of the bones in the articulation, and is lubricated by synovial fluid. However, the joint between two vertebrae is cartilaginous: this intervertebral fibrocartilage disc connects the vertebrae. The kinematics of the disc articulation are more complicated than those of the hip due to the action of this cartilaginous element which is situated between the bones. A healthy disc comprises two elements of different composition, structure and mechanical properties. In the centre of the disc is a spherical nucleus over which the vertebrae ‘oscillate’ (Figure 4). This oscillating movement is cushioned by the action of an exterior ring, the annulus fibrosus.

- Insert Figure 4 around here.

⁷ At least two mimetic-type discs are currently being used in FDA approved IDE (Investigational Device Exemption) clinical studies. If the results of these studies are favorable these mimetic discs could be commercialized in the US.

Mimetic-type artificial discs attempt to imitate the articulation properties of the anatomical disc in various ways (Figure 4). However, at this level there are uncertainties related to these properties, which include aspects related to the movement in the joint (kinematics) and aspects related to the loads applied and the movement (dynamics). The disc has viscoelastic properties, that is, its elasticity depends on the speed at which the load is applied. Viscoelastic materials present hysteresis (White and Panjabi, 1978). Hysteresis is the phenomenon of loss of energy when a material is subjected to successive cycles of charge and discharge. The phenomenon was observed for the first time in the vertebral disc, in 1951, when Virgin tested isolated discs from cadavers. It is this hysteresis of the disc that led to the assumption that, in addition to governing the movement of the two adjacent vertebrae, the disc articulation absorbs part of the load to which it is subjected. Therefore, when establishing the design parameters of an artificial disc, advocates of the mimetic principle refer to the 'load absorption' properties of the natural disc, which the hip-like disc, due to the nature of its operational principle (derived from the kinematics of a perfectly rigid, solid structure without viscoelasticity), cannot imitate. Thus, similar to vertebral fusion, absence of the capacity to absorb load in hip-like discs could lead to the 'adjacent disc degeneration syndrome'.

It is at this moment that new uncertainty appears. Since Virgin's (1951) study it has been proved that *isolated* discs (i.e., discs dissected from the vertebral column and studied individually) have viscoelastic properties. However, the magnitude of the effective load absorption in the entire vertebral column (if it exists), and in each disc articulation in particular, is unknown. The analogy of car wheels is illustrative: the viscoelastic properties of the material from which car wheels are made may be known,

but (if no adequate predictive models exist) only in simulations of the load conditions of a car, and on a predetermined surface, can the degree of load absorption of the wheel be assessed. In the case of the artificial disc, there are no mechanical or clinical tests capable of simulating conditions. As Le Huec et al. (2003) note, there are simply no data concerning the effective load absorption of a vertebral articulation, that is, the percentage of charge transmitted from one disc articulation to another. Thus, the theoretical arguments favouring one or other operational principles are marked by this fundamental uncertainty concerning the effective load absorption capacity of the disc. For advocates of the hip-like disc, the absorption of load in the anatomical disc (if it exists) is irrelevant, and the prosthetic restoration of movement is sufficient (Mayer, 2005). For advocates of the mimetic disc, as explained above, artificial discs that do not absorb load, lead to degeneration in the adjacent discs (Van Ooij et al., 2003). None of the review studies concerning the evolution of the artificial disc reference clinical trials that contribute evidence in either direction.

In uncertain situations, hybrids of two technologies can emerge (Geels, 2002; Utterback, 1994). This applies to the case of the artificial disc, for which we have described the high level of uncertainty about the differential performances of the hip-like and mimetic principles; as Szpalski et al. (2002:S67) unambiguously put it, in the history of the artificial disc ‘of course some devices attempt to combine both principles’. Other documents that provide more detail on technological aspects (such as the state of the art review of patents US5314477 and US7250060, or US patent application 20050251260) also refer to the hybridization of the two principles, hip-like and mimetic. In our analysis, we identify hybrid patents as those whose physical configuration combines both operational principles. Our criteria are exemplified by

hybrid patent US6001130, the oldest hybrid patent, finally developed commercially as the Bryan Disc.

- Insert Figure 5 around here-

This patent has a configuration typical of the mimetic operational principle:⁸ two elastomers,⁹ which imitate the nucleus and the annulus in the intervertebral disc (see Figure 4), and two small metal plates that act as the disc-bone interface, ensuring the stability of the implant. However, it also incorporates an important novelty with respect to the typical mimetic configuration, which is that the small plates can rotate relative to the elastomers, as in hip-like artificial discs (Figure 5) while, in mimetic operational principle discs, the small plates usually are joined to the elastomers within in the same mould - or by means of a specific process, such as vulcanization - which leaves no possibility for relative rotation.

4. DATA AND VALIDATION METHODOLOGY

Artificial discs are represented in several US patent classes (623.17 and its subclasses; 606.279 or 128.898); these classes refer not just to arthroplasty, but to other spinal implants using different operational principles, such as arthrodesis. So we built our database using key word searches¹⁰ and found 201 US patents granted for artificial discs before 2008. We searched for citations among these 201 patents. We added citations to

⁸ E.g. in patent US3867728, the oldest of the mimetic operational principle inventions and the oldest in the whole network.

⁹ Elastomer refers to materials with mechanical properties (e.g. hysteresis) similar to rubber.

¹⁰ We used the key words 'disc prosthesis', 'artificial disc' and 'arthroplasty' and conducted the search in the title and the abstract of the patents.

other kinds of medical products, to study the technological antecedents to our product (Mina et al., 2007). Our final database includes 1,535 patents and 6,130 citations. We included World Intellectual Property Office (WIPO), European and national patents in the cited patents, to catch the possible international origins of their antecedents.

Patent citation practices reflect national and legal differences (Meyer, 2000). We use US patents for our artificial disc search as they are the only ones used in connectivity analysis so far. This geographical bias has to be considered, since Europe has played an important role in the history of the artificial disc. We try to catch the historical influence of European developments in our narration of the evolution of the artificial disc. However, we should point out that there is a sort of ‘autonomous’ US trajectory since 160 of the 201 artificial disc patents are ‘pure’ US patents, that is, they belong to a family of patents¹¹ associated to a US priority date or to a WIPO priority date applied in North America. Also, 112 of these 160 patents have European ‘offspring’,¹² indicating that invention activity in the US has been influential in Europe; there is no reciprocal reverse influence, though, since of the original 201 patents only 41 have an ex-US origin.

In Invention 2, after the first innovation appears on the clinical market, we are interested in the top path content of reliable knowledge based on clinical use. Therefore, in Invention 2 our main results are based on comparison of the artificial disc patents filed before April 2005 (the filing date for the most recent granted patent in our sample), and the artificial discs marketed up to 2006 (Table 1). We proceeded as follows: we

¹¹ All documents with the same priority or combination of priorities belong to one patent family. These priorities could refer to national, European, US or international application dates.

¹² European or international patents which include European nations in their geographical range of protection.

collected all the commercially available artificial discs according to an industry report dated September 2006 (Engelhardt, 2006), and studied their physical structures based on the information provided in Kim et al. (2006). This is a clinical work that provides ‘an exhaustive review of the systems that have been proposed’ (Kim et al., 2006: xi). We classified the designs following the 10 criteria proposed by Miz (2006)¹³ and checked whether the designs in Kim et al. and the designs in the patents matched; this task was helped by the diagrams in the book and in the 53 patent documents selected by the connectivity algorithm.

We also used another method to check the correspondence between commercial products and patents. We studied the history of the development of each commercial artificial disc in the sources mentioned in Table 1, focusing especially on product owners and inventors. We then checked our patent database for owners and inventors, and whether the patents were similar to the physical structure of the corresponding products, following the procedure described above. There are several cases where checking the owners of patents required deep historical knowledge on transactions in the technological market. For example, in the Prodisc case, the 2006 owner of the artifact was Synthes, a US public company, but the project was originally developed by JBS, a small French company which, in 1997, was bought by Aesculap, a German company. In 2000 Aesculap entered a joint venture with Viscogliosi Bros, a New York venture capital company, to create Spinal Solutions, a company devoted to the development and commercialization of ProDisc. In 2003, Spinal Solutions was bought by Synthes for \$350 million (Marnay, 2004; Biondo and Lown, 2004). This example

¹³ These 10 criteria cover each one 2 or more design categories. All the dimensions combined constitute a ‘design space’ (Murmman and Frenken, 2006) of 6,384 different artifacts.

shows that this validation strategy requires in depth knowledge of *both* the technical aspects and the history of projects. Results and sources are presented below in Table 1. We found no patents for two products, Kineflex-L and Kineflex-C. We found a smaller proportion patents in use for the artificial disc technology than the proportion reported in Giuri et al. (2007). A possible explanation for this might be that this technology is far from maturity, as we will see in next sections; as technological and market uncertainty is greater in non-maturity stages, the number of abandoned projects grows (Agarwal et al., 2005).

- Insert Table 1 around here.

We double-checked only the 45 Invention 2 patents in the NETP. For the remaining 148 Invention 2 artificial disc patents in our database, we searched for owners and inventors in the patents database. We then compared the physical structure of these commercial artificial discs with selected patents to confirm their correspondence. We did not check the physical structure of all 148 patents.

In Invention 1, prior to the first innovation, we are interested in the presence in the top path of reliable knowledge developed in the performance tests conducted during development of the product. We searched for news about development tests in three scientific articles on the history of this implant (Szpalski et al., 2002; Bono and Garfin, 2004; Sakalkale et al., 2003), and checked whether the names associated with these projects matched the inventors of patents prior to the first innovation. We checked this for the eight 'Invention 1 patents' in our database.

For the connectivity analysis of the resulting citation network we use the Citpath software developed by Bart Verspagen. We consulted four experts to guide our search and comment on our results: two vertebral column surgeons (one of whom is the inventor on several patents that refer to artifacts similar to those discussed here), and the Chief Executive Officer and head of the research and development (R&D) department of a company in the sector, who together represent 40 years' of experience in the industry. Also, one of the authors of this paper worked in that same company for five years, as a manager of R&D projects.

5. CONNECTIVITY ANALYSIS OF THE ARTIFICIAL DISC

5.1 The network and the stages of technological evolution

A network weak component is a set of patents which are connected, directly or indirectly, by citations.¹⁴ The artificial disc patents citation network has only one component, which confirms the precision of our keyword search in finding a highly coherent field of technology. Connectivity analysis selects 53 patents to form part of the NETP, and 15 to form the top path. Figures 6, 7, 8 and 9 are snapshots of the 53 patents selected by connectivity analysis to form the NETP for the years 1973-1987, 1973-1997, 1973-1998 and 1973-2005. Various diagrammatic codes are included in the network diagrams¹⁵. The red/darker shaded nodes make up the top path of the network, that is, the path with the highest values of link connectivity in the network, and which

¹⁴ For a more detailed discussion, see Wasserman and Faust (1994: 109-110).

¹⁵ Only the French patent FR1122634 is not a US patent in the NETP. We have decided not to include country codes to improve clarity in representations of the NETP and the top path thereafter for clarity reasons. In next figures, FR1122634's label -situated on the top right-hand corner in Figure 9- is 1122634.

constitutes part of the NETP. The yellow/lighter shaded nodes represent the remaining patents selected by the NETP algorithm. The square nodes correspond to patents based on the hip-like operational principle; the circular nodes represent patents based on the mimetic operational principle; the triangular nodes represent ‘hybrid’ patents.

-Insert Figures 6, 7, 8 and 9 around here.

The intervals of the snapshots are marked by the divergent strategic patents in the top path. The first important strategic patent is US4759769, filed in 1987. From this patent, the network split into three branches. Of these, only the branch that ends with patent 6113637 is ‘selected’ among the post-1998 patents, being the only path along which knowledge flows between the two areas, pre and post-1998. After patent 6113637 there is a succession of small diversions from the top path due to truncation of the patent data in the most recent years (Verspagen, 2007; Hall and Ziedonis, 2001)¹⁶. In addition to these small diversions, there is a longer branch diverging from patent 6113637 which indicates that this is a strategic patent.

In Section 2.3 we discussed the stages in the evolution of technology which are marked by these divergent strategic patents. The first stage is depicted in Figure 6, which shows the network of the evolution of top paths from 1973 to 1987. In the latter year the first strategic patent was applied for (US4759769). This 1973-1987 stage is clearly related to Invention 1 (prior to the first innovation), as the first artificial disc, the SB Charité, was commercialized in 1989.

¹⁶ We thank an anonymous referee for pointing this out.

The three red squares/nodes at the top right of the figure are the technological antecedents to the artificial disc. Patent FR1122634, US3462765 and US3593342 describe finger and femoral prostheses which use synthetic materials similar to those used to construct the first mimetic artificial disc prostheses. The next patent in the top path is US3867728; although there is no record of use in humans of the disc prosthesis described in this patent, it is associated with the first animal model in the history of the artificial disc (Urbaniak et al., 1973). The design of this patent is repeated in several mimetic discs: a central piece made of an elastomer with viscoelastic properties, and two plates simulating the anatomic vertebral plates.

The next patent in the top path (US4349921) refers to a mimetic disc owned by Dr David Kunz, who invented and produced this prosthesis in his hospital workshop, to treat pathologies of patients' vertebral columns, and who operated on more than 300 individuals without regulatory permission. In 1986, the health authorities barred Dr Kunz from practising on the basis that the operations involved a surgical procedure that had not been scientifically validated. Kunz's trial showed good results from his surgeries and he claimed that the many citations to his patent were proof of the importance of his work (Jory, 2007). The next patent in the top path, US4759769, is a strategic patent which is analysed later. Here we point out that the artifact described is related to the establishment of the first systematic protocols of mechanical testing in the history of the artificial disc.

Of these three patents, two include US priority data and the third uses Canadian priority data.¹⁷ These three US patents are related to mimetic prostheses. In Europe, on the other hand, this first stage was dominated by the hip-like design. The most frequent design in these years was the failed prosthesis invented by Fenström (a Swedish surgeon), which can be considered an ‘archaic’ predecessor of the hip like principle (Bono and Garfin, 2004: 148S). All of the 100 experimental implants conducted at the end of the 1950s failed in the long-run (García, 2002); we found no national or international patents associated with this device. Apart from this precedent, the first important hip-like project began in 1982 in Charité Hospital in East Berlin, when the surgeons Kurt Schelznack and Karin Buttner-Janz started the design of the SB Charité, the first artificial disc to be implanted commercially in France, in 1989. In 1986, Waldemar Link, a West Germany orthopaedic implants company, joined the project. The second artificial disc to be commercialized, marketed as Prodisc, began development in the early 1980s in France (Marnay, 2004). None of the four US patents referring to SB Charité (US5556431 and US5401269) or Prodisc (US7204852 and US5314477) were selected by the connectivity analysis, for either the NETP or the top path.¹⁸

The second stage from 1987 to 1998, falls between the first and second strategic patents. In North America, two important mimetic projects were developed in these years in US (Szpalski et al., 2002; Bono and Garfin, 2004; Sakalkale et al., 2003). The Acroflex disc project was developed in 1986-1999 by Acromed, a spinal implants

¹⁷ The owners of these patents are US companies (US3867728), Canadian public laboratories (US4759769) and Canadian individuals (US4349921)

¹⁸ There may be several patents referring to the same product. In Section 5.3 we discuss the implications of this for our validation exercise.

company in Ohio.¹⁹ The implant was employed in three experimental series in 1988, 1993 and 2002 and Acromed applied for the first artificial disc IDE (Investigational Device Permission) to the FDA in order to commercialize the implant in USA following these clinical studies. However, the Acroflex implant failed in all three of the experimental series, mainly due to problems in the interface between the elastomer and the metallic plates, and IDE permission was withdrawn (Fraser et al., 2004).

The other important mimetic project started (and abandoned) in this period was led by Dr Casey Lee with participation from Rutgers University and Johnson & Johnson. Despite exhaustive descriptions of good results from the in vitro tests conducted in the early 1990s, the project was abandoned because of manufacturing difficulties (Bao et al., 1996). Patents US5674294, US5370697 and US5320644, the yellow/light shaded nodes at the right side of the 1987-1998 snapshot of the NETP, show designs very similar to those developed in the Acromed and Lee projects (Figure 7).

Following exploration of these branches based on mimetic designs until 1997, in 1998 the top path finally chose a hip-like branch to continue the technology evolution (Figure 8), leaving the other branches to be dead-ends where technology did not advance. In the years up to 1998, the first good results from SB Charité - the hip-like prosthesis - were published in various US scientific journals. In the first part of the 1990s SB Charité began diffusion to Italy and the Netherlands (Mutescu, 2002b). In 1994, the first medium-term follow-up study was published, reporting good results in 93 patients

¹⁹ Engelhardt (2003a: 7) says that “it became part of the AcroMed culture to ridicule” SB Charité because its incapability to reproduce the viscoelastic behaviour of the anatomic disc.

(Griffith et al., 1994), and soon after, good results were reported in Italy and France (Cinotti et al., 1996; Lemaire et al., 1997).²⁰

All the nodes in the hip-like branch of the top path in the 1987-1998 period present a similar configuration, with a two-piece, hip-like articulation. Two of the four nodes in this branch were developed and eventually introduced to the market: patents US5425773 and US6113637 were commercialized in Europe in 2002 under the brand names 'Maverick' and 'Prestige' (Biondo and Lown, 2004) by Medtronic, a US company.

The third and most recent stage is from 1998 to 2004 (Figure 9). This stage is marked historically by the consolidation of the hip-like principle in the market. Figure 10 represents the evolution of sales of artificial discs in Europe. Besides the sales take-off of hip-like discs in Europe, the North American market was finally accessed: in 1997, Waldemar Link (the company in charge of the development and commercialization of the SB Charité since 1987) created Link Spine Group to introduce the prosthesis in North America. Also in 1997, Link attended the North American Spine Surgeons (NASS) Congress to present SB Charité. In 1999 an IDE application for Charité was made and granted by the FDA, the first successful application since Acroflex's failed IDE; the experimental trials showed good results, and the FDA finally approved commercial utilization of an artificial disc in the US in 2004. In this same year, Biondo and Lown (2004: 18) state that there were:

²⁰ Griffith et al. (1994) and Cinotti et al. (1996) published their results in *Spine*, the subspecialty leader journal for the treatment of spinal disorders. Lemaire et al. (1997) published their results in *Clinical Orthopaedics and Related Research*. Both journals were introduced to enable communication for the North-American associations of surgeons which eventually become international associations.

‘more than 2,000 international spine surgeons that have been trained on spine arthroplasty products, while there are more than 150 US surgeons participating in spine arthroplasty clinical trials. Simply put, an industry has been realized’.

- Insert Figure 10 around here.

With FDA approval for SB Charité, the trends were towards growth in the market for the artificial disc. As Lieberman (2004) points out, there were expectations of a ‘disc bubble’. For example, JP Morgan published a report which estimated that the artificial disc would achieve 2.8% of spinal implants market in 2005, 7.3% in 2006, 16.2% in 2007, reaching 47.9% in 2010. This percentage would represent sales ranging from \$1400 to \$3000 million (Weinstein et al., 2003).

Consolidation of clinical use of the hip like micro-paradigm is reflected in the composition of the top path after 1998: three of the five patents following the last strategic patent (US6113637) belong to the hip-like principle. Last two hybrid patents could reflect a future invention shift. Of the five patents in this section of the top path, two (US6368350 and 6986789) became a commercial product.

We have seen that the top path patents reflect the different kinds of reliable knowledge influencing each stage of the artificial disc evolution. In the first stage, Invention 1 has no feedback from clinical use. Reliable knowledge comes from tests (US3867728 and US4759769) or other forms of vicarious use (US4349921). In the next stage, the transition from Invention 1 to Invention 2 is reflected at first in the persistence of

mimetic designs in the NETP; after 1997 the top path reflects the emergence of reliable knowledge in the clinical use of the hip-like principle. This trend is consolidated in the last stage, from 1998 to 2005, when the hip-like design becomes clinically established worldwide (Figure 11).

- Insert Figure 11 around here.

5.2 A tale of two (strategic) patents

Figure 11 shows that divergent strategic patents mark the end and beginning of invention stages. The first of our divergent strategic patents is US4759769, from which stem the three pre-1998 branches of patents. Although the disc associated with this patent did not progress to the commercialization phase, it was the artificial disc design that was ‘most thoroughly tested’ over the years, in the course of a development project (Bao and Yuan, 2000: 3). The patent inventors are also the authors (Hedman et al., 1991: S256) of the most highly cited scientific article in our patents database, which describes the mechanical tests devised to trial the artificial disc prosthesis described in the patent. It proposes the parameters for experimentation related to this prosthesis, but also others for artificial discs in general; the technical specifications for these tests were adopted 15 years later by rule F2356 of the American Society for Testing and Materials (ASTM) to regulate the mechanical behaviour of artificial discs (Dooris et al., 2005). Hedman et al. (1991: S256) emphasize the importance of in vitro trials in experiments on artificial discs: ‘The design-analysis redesign loop should be well travelled before the first clinical trial to minimize the iterations of redesign after clinical trials have

begun... The purpose of this paper is to present a broad range of pre-trial design criteria'. Thus, we would claim that the strategic status of this patent is based on its fundamental contribution to the reliable knowledge during the development of the product.

The second strategic patent in our database is US6113637, the final patent in the branch starting from US4759769, which is selected by the post-1998 patents to connect the two areas of dispersion. As already mentioned, this patent is for a hip-like artificial disc. The Prestige disc is distinctive in that it was the first cervical disc implant in regular clinical use in Europe and the US.

Although in most cases, our patents do not distinguish between the lumbar and cervical areas of the vertebral column, some prostheses are designed specifically for one or other of these two areas. Of the 53 patents in the NETP, 42 are designed for use in both the lumbar and cervical vertebral areas, for example, patent US589941, which also belongs to the top path and has a similar physical configuration to the Prestige disc. Four patents relate to designs exclusively for the lumbar area, and seven relate to prostheses for the cervical area, including the Prestige disc. There is no noticeably different trend given that three of the cervical patents were applied for before 1998 (the year of the Prestige disc patent application) and three were applied for after that date.

However, a wider perspective again is provided by the history of real and vicarious use, which shows the real evolution of the artificial disc. The majority of the painful symptoms associated with DDD occur in the lumbar area. The first theoretical description in the scientific literature, of substitution of an anatomical disc with an

artificial implant, refers to the lumbar area (Nachemson, 1962). The first trials in animals (Urbaniak, 1973) and the first protocol for in vitro trials (Hedman et al., 1991) also refer to lumbar discs. The first discs to be commercialized (pre-1998 and pre the Prestige disc) were designs for the lumbar area.

However, the relative simplicity of the cervical surgical technique re-focused inventive activity on this area in the last years (Engelhardt, 2003b). Moreover, while lumbar surgeries are traditionally performed only by orthopaedic surgeons, the cervical technique is performed by neurosurgeons, as well as orthopaedic surgeons (Mutescu, 2003). This resulted in increased demand for cervical treatments (Lieberman, 2004). In our view, the strategic position of patent US6113637 is due to the status derived by the Prestige disc as the first cervical disc to be used commercially, which provided reliable knowledge to post-1998 development projects and resulted in greater attention to the peculiarities of specifically cervical designs. In a 2008 industry report, 12 development projects for cervical discs and 6 projects for lumbar discs, were reported to be in the clinical trial phase (O'Reilly, 2008).

Thus, both strategic patents played an important role in the history of the artificial disc. However, their importance is qualitatively different. Both mark the transition from Invention 1 to Invention 2, that is, the transition between different regimes of reliable knowledge. The emphasis in the first strategic patent is on the testing criteria applied during technological development of the product. The emphasis in the second is that it extends the possibilities of this procedure to many more surgeons. This change from 'supply' to 'demand' factors highlighted by these strategic patents mimics the transition

from vicarious use developed in R&D projects (Invention 1) to commercial use in clinical procedures (Invention 2) as fundamental sources of reliable knowledge.

5.3 Validation of the methodology

Table 2 presents the results of our external validation exercise. We claim that the importance of the patents in the top path is correlated to their ‘reliable knowledge’ content in the different stages of technological evolution. In Invention 1, where there is no feedback from innovations in the market, the reliable knowledge is based on the results of experimental tests, prior to clinical use. The three top path artificial disc patents are related to prostheses proved in pre-clinical tests and irregular clinical use. We find no such correspondence between the other artificial discs patents in this period and the development projects referred to in Szpalski et al. (2002), Bono and Garfin and Sakalkale et al. (2003). These results are reflected in the first row of Table 2.

- Insert Table 2 around here.

In Invention 2, after the first innovation, feedback comes mainly from experience of clinical use. In the case of Invention 2, we can measure the validity of this hypothesis with the magnitude of ‘innovative effectiveness’. We measure the innovative effectiveness as the proportion of top path patents that eventually finally are transformed from inventions to innovations.

The most appealing characteristic of the patents in the Invention 2 top path (post-1987) is the high proportion of patents associated with products that were used clinically. According to our historical study (Table 1), 44% (or 4 out of 9) of the artificial disc patents in the Invention 2 top path, are examples of ‘innovative effectiveness’.

Of the remaining NETP Invention 2 patents (36), four are for designs that are used regularly in clinical practice. Three of them describe incremental improvements to the same product. Patents US6001130 and US6156067 are continuations of patent US5674296, the first patent for the Bryan artificial disc. When the approval process for the original patent is still ongoing, a patent that is a continuation by the same inventor can take the priority date of the original patent once it receives final approval.²¹

Thus, in the remaining Invention 2 NETP, ‘innovative effectiveness’ differs depending on whether we are counting patents or commercialized products. However, as results are quite similar for patents and products we deal thereafter only with products²². These 36 patents cover 2 commercialized products (5’55% of ‘innovative effectiveness’). For the remaining 148 patents for artificial discs in our database ‘innovative effectiveness’ is 4.72% (7 products for 148 patents).

Thus, the measure of connectivity identified by the top path algorithm identifies reliable knowledge in Invention 2 patents, which have passed through all the required approval processes to become commercial products in regular clinical use. The remaining NETP

²¹ This information was taken on 18 October 2008 from the Manual of Patent Examining Procedure (MPEP), available on the US Patent and Trademark Office website: <http://www.uspto.gov/web/offices/pac/mpep/index.htm>

²² Patents count show slightly greater “innovative effectiveness” than products count in the remaining NETP patents. Results for patents count are disposable by e-mailing the first author of this paper.

patents and the remaining patents in our database have lower and similar values for ‘innovative effectiveness’. These results are coherent with the logic underlying the construction of the network and the evolution of top paths described by Martinelli (2008) and Verspagen (2007), in which non-top-path NETP patents are ‘dead ends’ where the technology cannot continue to evolve. Therefore, our results seem to corroborate the external validity of connectivity analysis of patent citations networks; in this case, it seems that the validity of connectivity analysis is not threatened by the interferences described by Alcacer and Gittleman (2004, 2006) since our study demonstrates that the top path includes a high proportion of the most important patents in the technological evolution of the artificial disc, that is, those which content technological reliable knowledge²³.

Table 2 present disaggregated data for the 1987-1998 and 1998-2005 Invention 2 snapshots. The former period represents the transition from Invention 1 to Invention 2. There is less ‘innovative effectiveness’ in the last Invention 2 stage (1998-2005) for all the sections of our sample: the top path, the remaining NETP patents and the remaining patents in our database. Therefore, it seems more difficult for connectivity analysis to catch the reliable knowledge in recent patents.

Although the comparison between connectivity analysis and patent citations count is not the main objective of this work, some comments are due. Fontana et al. (2009) show that the patents identified by connectivity analysis are not necessarily the most cited patents in the sample. In their case, 7 of the 13 top path patents are among the 20 most

²³ In this specific case, the absence of interferences could be due also to the special characteristics of the medical technologies, where the share of citations added by patent examiners tends to be smaller than in most other sectors (Alcacer et al., 2009). We thank an anonymous referee for pointing this out.

cited patents in their sample. In our case, only 4 of the 14 top path patents were among the 20 most cited patents. It is interesting also that the two most frequently cited artificial disc patents are not selected by the connectivity analysis – for the NETP or the top path. These two patents are the initial patents for SB Charité (US 5401269) and ProDisc (US5314477), the first two artificial discs to be developed and used clinically in Europe.

Fontana et al. (2009: 334, fn 22) refer to the case of a patent selected by connectivity analysis because of its importance ‘*at that point of time*’ (italics in original), meaning that it is what some refer to as ‘real time’ importance rather than ex-post importance (Consoli and Mina, 2009; Rizzo, 2000). In our case, connectivity analysis catches the importance of the historical contingencies of the US technological evolution, which originally was more focused on mimetic projects which ultimately failed. It was not until the late 1990s, contemporary with the first US published scientific results for clinical outcomes of European hip like prostheses, that the direction of US top path evolution changed from mimetic patents to hip like designs. This might be the reason for the notable absence of US patents for the SB Charité and ProDisc prostheses, which are the two most frequently cited patents, but which are not present in the NETP or the top path. The filing dated of these patents (respectively 1991 and 1993), are contemporaneous with the major effort in US mimetic project developments. The ex-post success of the products associated with these two patents seems to be captured best by ‘pure’ patent citation count.

6. CONCLUSIONS

Concerning the knowledge dimension of technological evolution, the historical account presented here seems to corroborate the external validity of connectivity analysis of patent citations networks. Our study demonstrates that the top path includes a high proportion of the most important patents in the technological evolution of the artificial disc, that is, those containing reliable technological knowledge. By contrast, non-top path patents in the network can be seen as ‘dead ends’ where the technology cannot continue to develop.

On the conceptual side, connectivity analysis also shows how invention-innovation dynamics act throughout the evolution of technology, from the stage where reliable knowledge is built during development of the product by vicarious users (Invention 1, prior to the first innovation), to the stage where the reliable knowledge comes from the commercial use (Invention 2). In the case of the artificial disc, Invention 1 patents reflect the mimetic efforts of the first US development projects (1973-1987), which ultimately failed. In the 1987-1998 period, after the clinical introduction of the hip-like disc, the network of citations accounts for the transition from mimetic to hip-like patents. In the last stage (1998-2005), hip-like patents in the top path reflect the hegemony of the hip-like principle in the clinical use (Invention 2 regime).

Recent works have questioned the use of patent citations as a measure (Alcacer and Gittelman, 2004, 2006; Gambardella et al., 2008). The validity of connectivity analysis of patent citations, corroborated in this work, may trigger a renaissance in the use of this kind of patent data.

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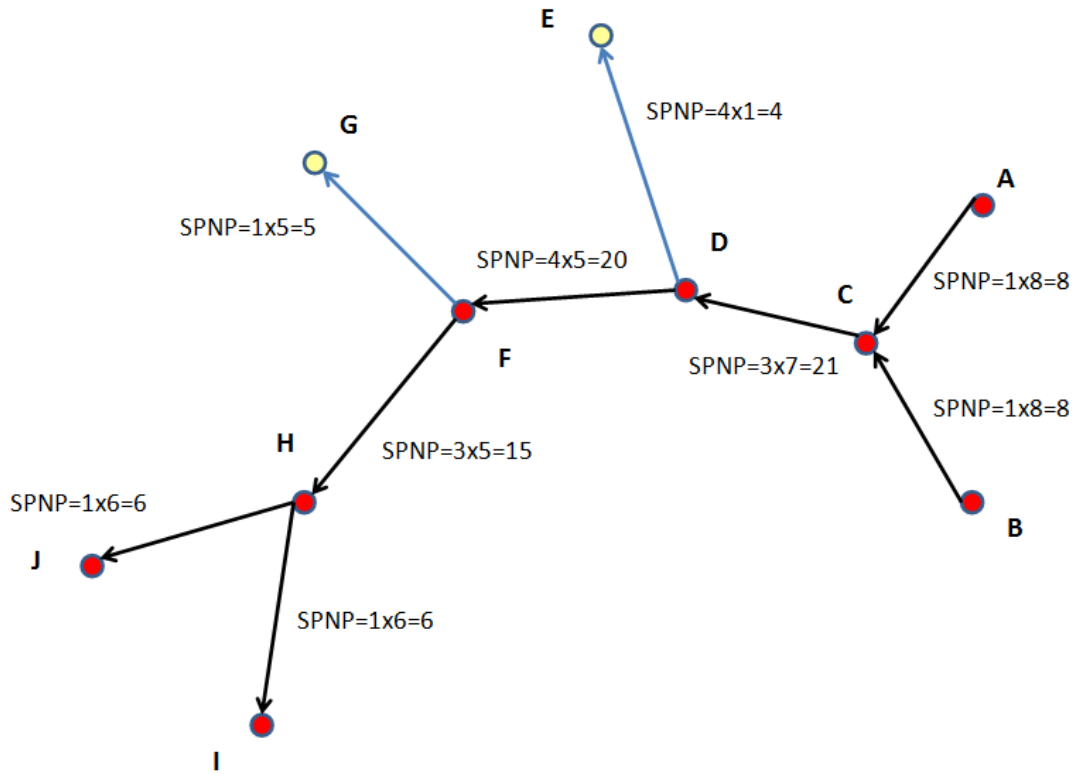


Figure 1. Calculation of SPNP. The main path is in black. Source: Fontana et al. (2009)

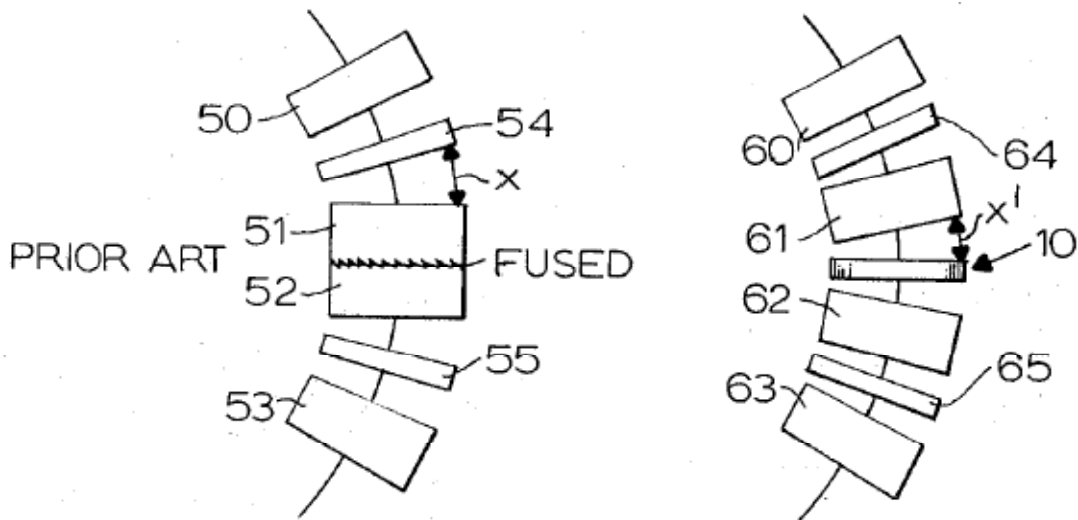


Figure 2. On the left, the fused vertebrae in an arthrodesis. On the right, the degenerated disc is replaced by a prosthesis. In the arthrodesis the movement of the fused articulation must be incorporated into the adjacent discs (x). In the arthroplasty, the movement is less and similar to the anatomical movement (x') (Source: US3867728).

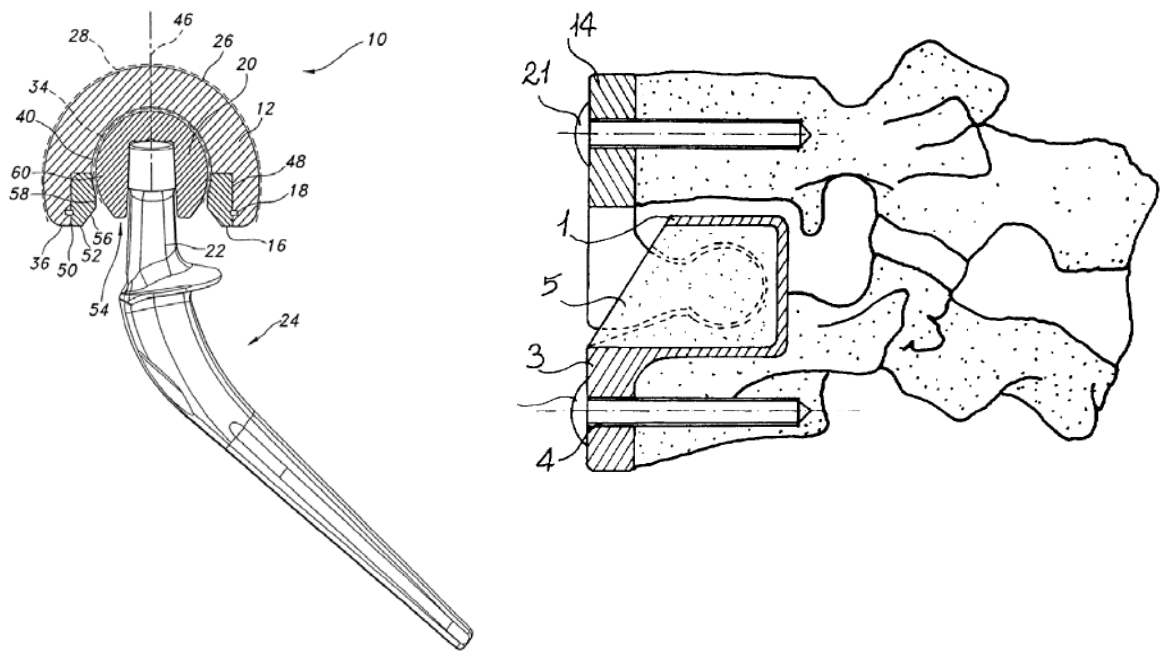


Figure 3. On the left, a hip prosthesis. On the right, a disc prosthesis following the 'ball-and-socket' principle of hip implants (Source: US6986792 and US5755796).

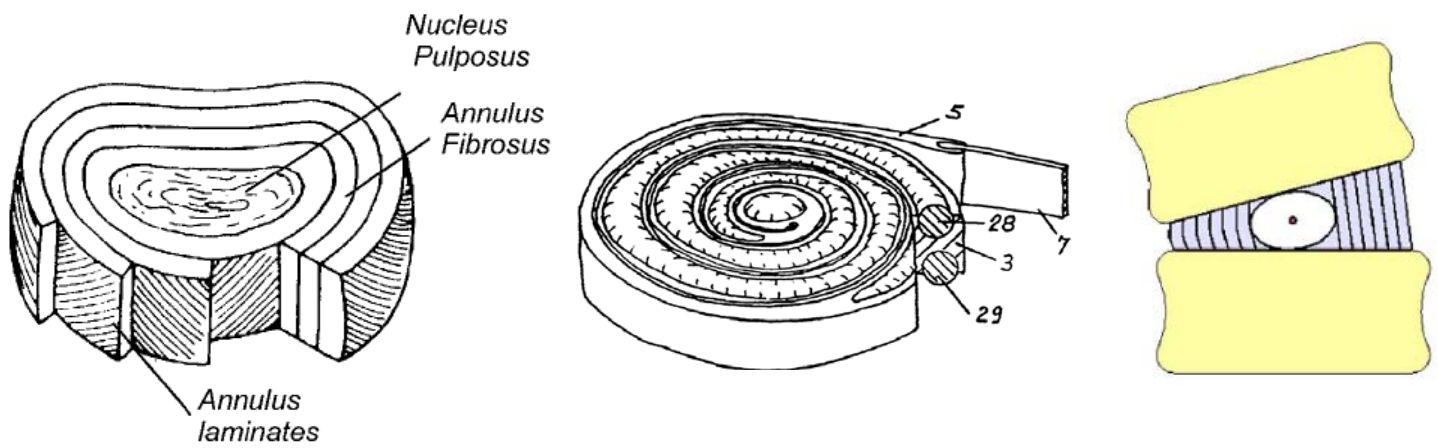


Figure 4. The diagram on the left shows an anatomic intervertebral disc. The diagram in the center shows a 'mimetic design' based on the reproduction of the viscoelastic properties of the anatomical disc, using materials such as synthetic elastomers (Source: Eijkelkamp, 2002 and US6610094). The diagram on the right shows a representation of the kinematics of the articulation.

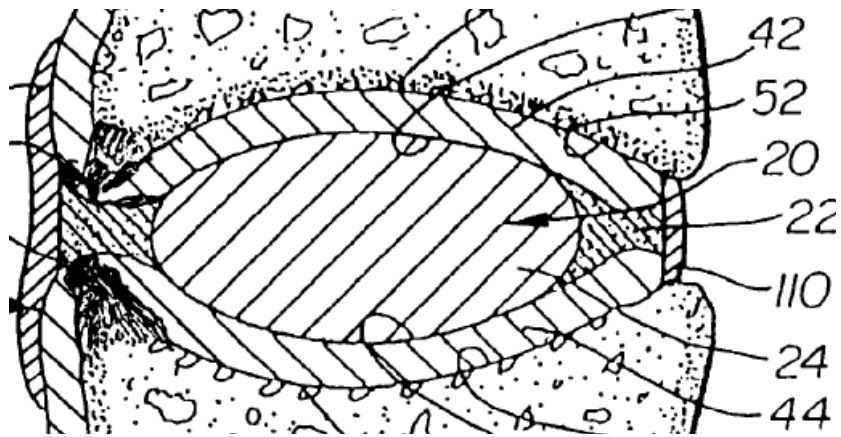


Figure 5. The hybrid patent US6001130. Elements 20 and 22 are elastomers, as in mimetic operational principle patents. However, instead of being joined to small plates 42 and 44, they move over them, as in hip-like patents.

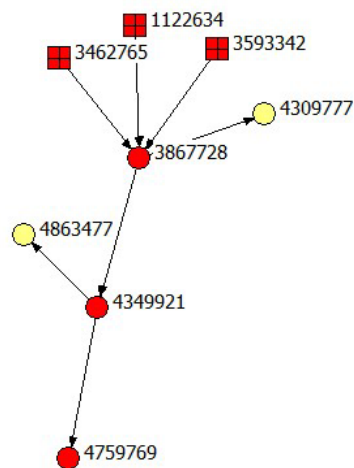


Figure 6: The Network of the Evolution of Top Paths (NETP) 1973-1987

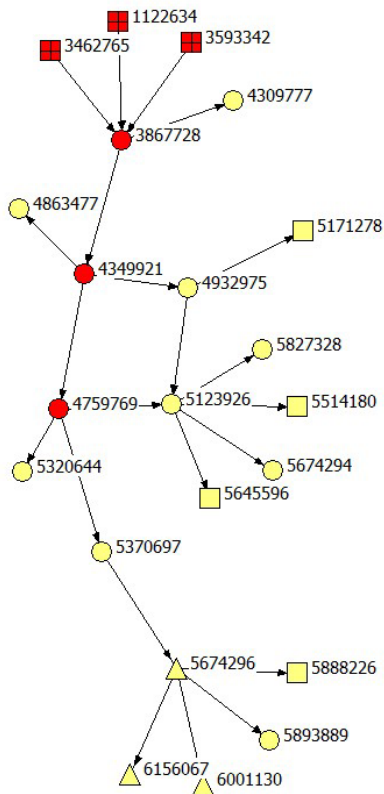


Figure 7: The Network of the Evolution of Top Paths (NETP) 1973-1987

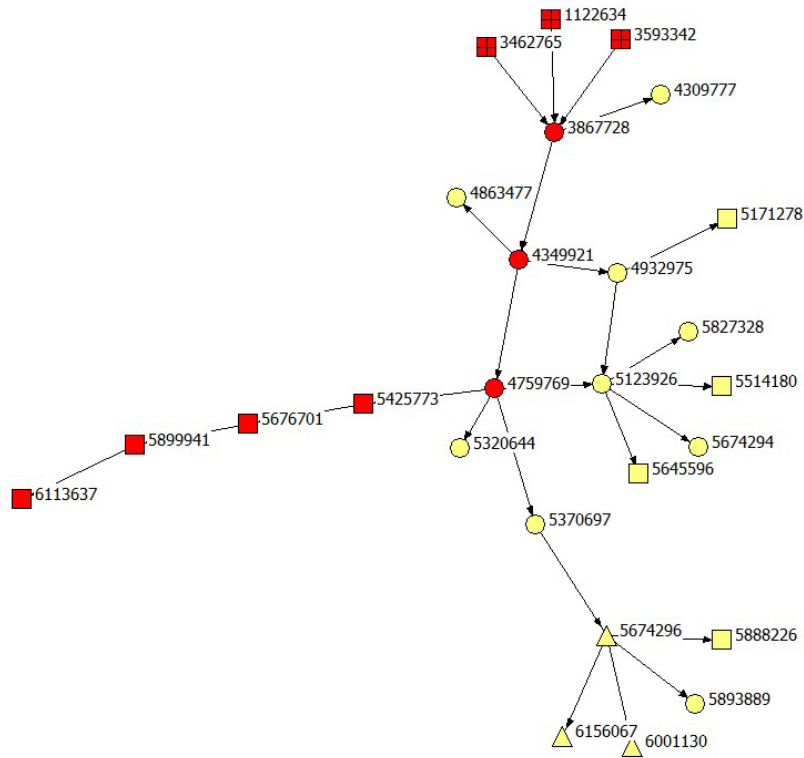


Figure 8: The Network of the Evolution of Top Paths (NETP) 1973-1998

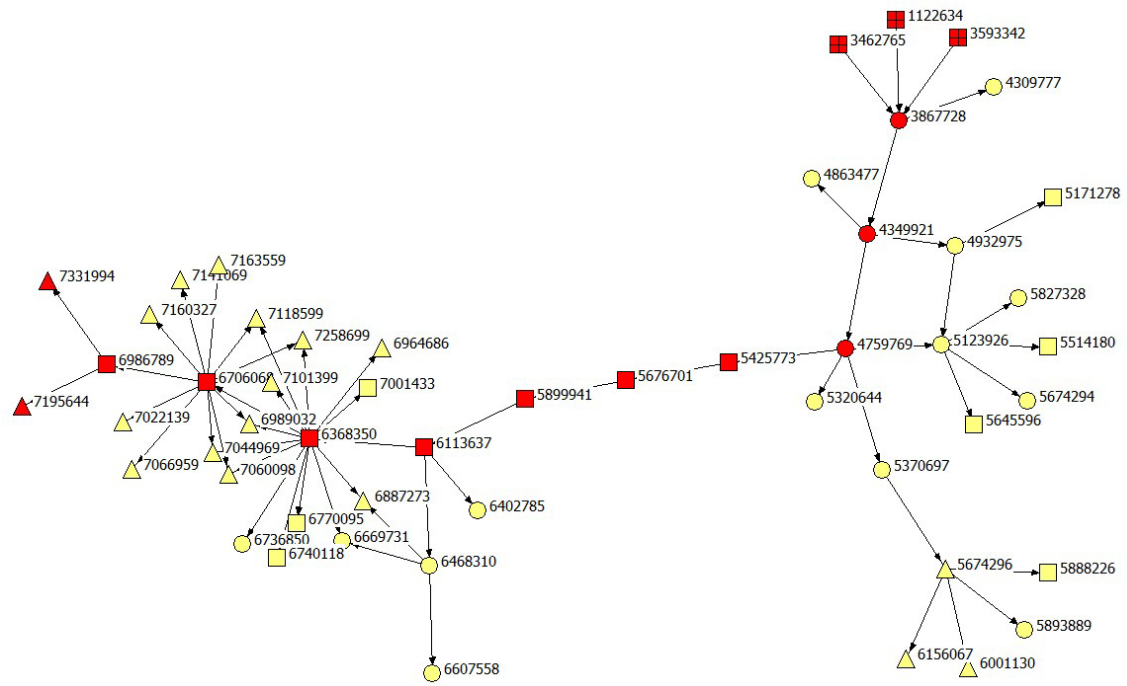


Figure 9: The Network of the Evolution of Top Paths (NETP) 1973-2004

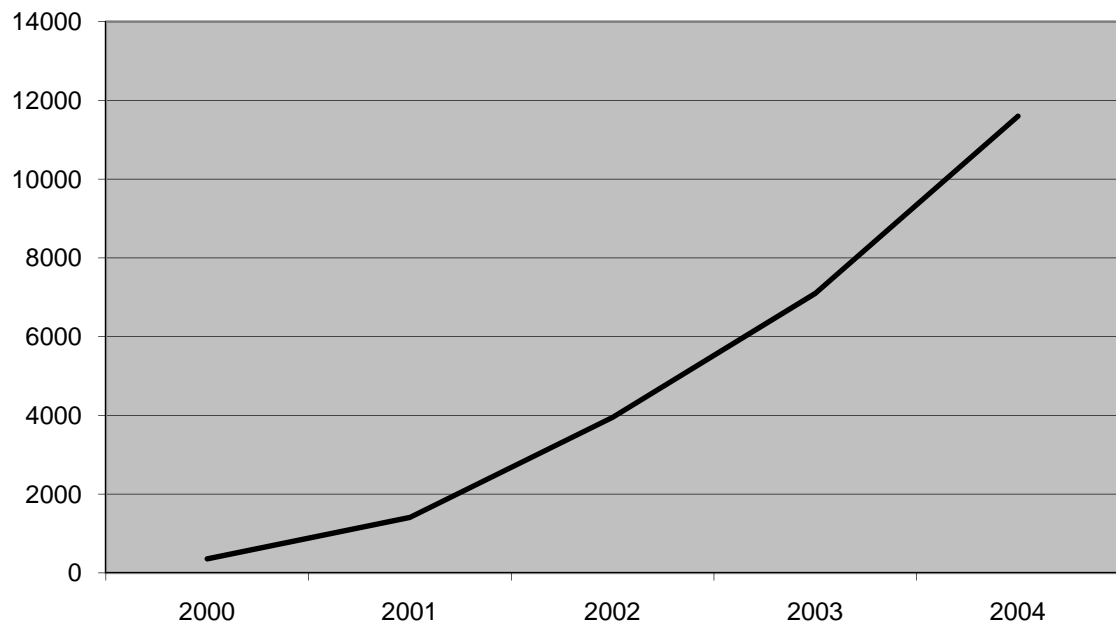
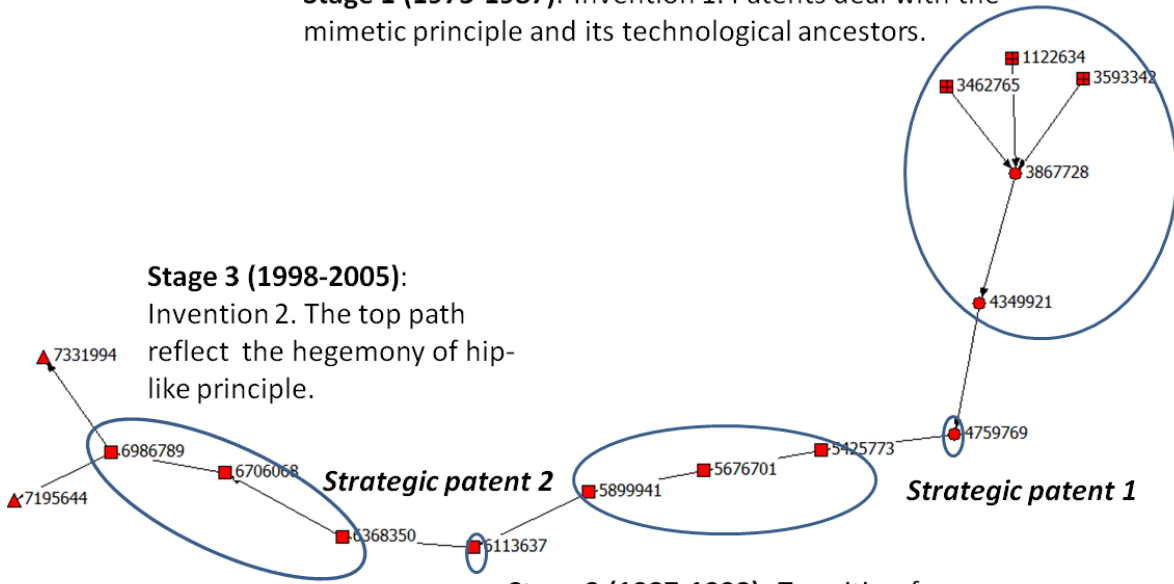


Figure 10: Artificial discs sold in 2000-2004.

Stage 1 (1973-1987): Invention 1. Patents deal with the mimetic principle and its technological ancestors.



Stage 2 (1987-1998): Transition from Invention 1 to Invention 2. After some exploration in the new mimetic designs, top path patents adopt the hip-like principle.

Figure 11. The stages of technological evolution in the top path.

<u>Product (Company)</u>	<u>Associated patents</u>	<u>Sources for the history of the associated R&D project</u>	<u>Situation of the patents in the citation network</u>
PCM (Cervitech)	7175662 7267691 7001432	Biondo and Lown, 2004*	Rest of artificial disc patents database Rest of artificial disc patents database Rest of artificial disc patents database
PRESTIGE (Medtronic)	6113637 6540785 (Continuation of 6113637) 7276082	Robertson, 2006 **	Top path Rest of artificial disc patents database Rest of artificial disc patents database
KINEFLEX -L(Spinal Motion)	-	Hähle et al., 2007**	-
PRODISC L (Synthes)	7204852 5314477	Mamay, 2004 +	Rest of artificial disc patents database Rest of artificial disc patents database
ACTIVE (Aesculap)	6986789	Yue and Garcia, 2007**	Top path
CHARITE (Johnson&Johnson)	5556431 5401269	Link, 2002**	Rest of artificial disc patents database Rest of artificial disc patents database
KINEFLEX -C (Spinal Motion)	-	See Kineflex-L	-
PRODISC C (Synthes)	See Prodisc-L	See Prodisc L	See Prodisc L
DYNARDI (Zimmer)	6368350	Biondo and Lown, 2004*	Top path
A-MAV (Medtronic)	5425773 5562738 (Continuation of 5425773) 6740118	Mathews et al., 2004**	Top path Rest of artificial disc patents database NETP
BRYAN (Medtronic)	7025787 5674296 5865846 (Continuation of 5674296) 6156067 (Continuation of 5674296) 6001130 (Continuation of 5674296)	Mutilescu, 2002+	Rest of artificial disc patents database NETP Rest of artificial disc patents database NETP NETP

Sources: * Industry report ** Scientific article or book chapter + Published interview with inventor.

Table 1. Correspondence between products and patents of commercialized artificial discs.

	Top path	Rest of the NETP	Rest of the artificial disc patent database
Invention 1 (content in reliable knowledge generated in product development).	100%	0%	0%
Invention 2 (innovative effectiveness) 1987-1998	50%	7.14%	8.33%
Invention 2 (innovative effectiveness) 1998-2005	40%	0%	3,5%
Invention 2 (innovative effectiveness) Total	44,44%	5.55%	4.72%

Table 2. Content of reliable knowledge in patents.