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THE CIVILISING TENSION AT THE HEART OF MARKET-MAKING: A CASE STUDY OF THE STENT INDUSTRY

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ABSTRACT

We are interested in the emergence of new markets. While the literature contains various perspectives on how such new markets come to be, the dynamics of the marketization process are less clear. This paper focuses on the development of stent technology and examines the activities characteristic of its emerging market. We identify four market 'moments': a *mutable marketing* moment prior to the point of disruption; two parallel moments at the point of disruption – *internecine marketing* between emergent competitors, and *subversive marketing* between those competitors and established actors; and finally, a *civilized marketing* moment. We conclude that emergent competitors operate two distinct strategies at the point of disruption. Also, legal activities are central to marketization dynamics during this period. In terms of process, while creative destruction may broadly describe the move from disruption to acceptance, there is a period of *creative construction* prior to disruption, when the new market is coming into being.

Keywords:

Market-making; civilized marketing; stent technology, legal activity, longitudinal case study; translation.

THE CIVILISING TENSION AT THE HEART OF MARKET-MAKING: A CASE STUDY OF THE STENT INDUSTRY

Introduction

The question addressed in this paper is how new markets emerge and are constructed. This immediately leads to further questions such as: What is a 'new market' and how does it differ from other markets? Are new markets deliberately constructed, or do they emerge in an *ad hoc* fashion? And what is the appropriate method to interrogate these broad questions?

The reflexive, emergent nature of the phenomenon warrants a particular mode of inquiry. Since marketization is an ongoing accomplishment – and even though any 'market' is worthy of study – studies of new markets, where new objects, actors, relationships and structures come to be, seem especially appropriate. Moreover, market-making processes are probably best inquired into through in-depth, empirical, longitudinal case studies. In particular, such studies should preferably collect data over an extended time period because the processes are unlikely to be apparent over short time horizons.

This paper reports on a study of marketization processes associated with the emergence of stent technology, stents, corporate actors and markets. The research method adopted was a *longitudinal case study*, which we felt was an especially appropriate way of inquiring into the phenomenon. Our perspective is influenced by Latour, Callon, Law and other actor-network contributors who advocate the detailed study of actions, over time, through which actors become powerful, and things – including markets – come to be (Latour, 1991; Callon, 1998). Within such a setting, there are several units of analysis of interest, including the firm, industry, product and market.

The relationships between these actors and entities have emerged as important in a range of literatures, for example, in terms of market-making (e.g. Araujo, 2007; Araujo, Finch and Kjellberg, 2010), competitive dynamics (e.g. Porter, 1979; Prahalad and Hamel, 1990; Das and Van de Ven, 2000; Beard, 2002; He et al, 2006) and the diffusion of new technologies (e.g. Rogers, 1962/1995; Davies, 1979; Robertson et al,

1996; Geroski, 2000; Dopson, 2005). So to frame our project, we focused on a definable market. Having considered different possibilities, we settled on a study of the stent market.

Stents – small tubes, usually metallic – are 'less-invasive' medical technologies, delivered by flexible catheters, with balloons often used to expand them in the clogged arteries they are designed to help clear. Coronary stents, which frequently obviate the need for open-heart surgery, were first tested in humans in 1986, commercially launched in the US in 1994, and were followed by drug-eluting stents (DES) – launched in 2003 in the US. Our study examines the market-making processes (e.g. Fligstein, 1996; Rosa, et al, 1999; Harrison and Kjellberg, 2010) associated with this product. As the characteristics of these processes were not clear, *a priori*, and as the primary focus of the research was the dynamics of these processes as the market developed, it was inappropriate to delineate the scope of the research in terms of possible characteristics such as scale or constitution.

Defining a start point and duration for the market-making processes presented a particular challenge. We utilise data from several decades prior to the patenting of the first balloon-expandable stent (in the USA) in 1985, until around the time when drug-eluting stents were introduced, in 2005. Evidence is presented to illustrate how the stent product began to impact on an existing market – the coronary artery bypass graft (CABG) market – as this period progressed. This situation represents the essence of Christensen's concept of 'the point of disruption' (e.g. Bower and Christensen, 1995; Christensen 1997; Christensen and Raynor, 2003) in technological terms.

Our actor-network approach meant that, rather than centering on one or other domain, we collected data on the product, the firms, the industrial context, the regulatory environment, related technologies, legal moves, and so forth. Consequently, a large amount of data relating to marketization processes over time was collected and analyzed. Our main data sources included the firms themselves, regulatory bodies, industry association publications, academic journals, and market reports. For example, we accessed several years of financial data for each of the firms listed, as well as product information, previous case studies and newspaper articles. We utilized several commercial, governmental, regulatory and academic

databases to construct a comprehensive record of events. These included FDA data, the National Hospital Discharge Surveys in the US, industry reviews, medical device industry representative associations, and product-based and clinical sources.

In addition, we conducted eight interviews with senior practitioners – both managerial and technical – in the industry, and two technical experts external to the industry. These interviews occurred during a period of substantial turmoil in the industry, as the launch of the second-generation products was imminent. As a result, it was difficult to gain access to the firms, and interviewees' demeanours were frequently reserved. Regardless, the interviews were useful in that they confirmed the issues of importance, facilitated an exploration of their details, and contributed to a more refined understanding of the case.

The study followed an inductive approach (Locke, 2007) in that it induced theoretical concepts and relationships through repeated analysis and synthesis of the empirical data.

Stent Market Case Overview

Some diversified firms (e.g. Johnson & Johnson; Abbott Labs) have entered the stent market relatively recently in terms of their own histories, while others were established as medical device firms in the 1950s and 1960s (e.g. Medtronic). In contrast to established firms entering the market, some corporate entities (e.g. Boston Scientific, 1979; Guidant, 1994) were established specifically to compete in this market. A summary of the dominant corporate entities in this market is provided below (see Table. 1, below). The data represents a snapshot of the market at a relatively advanced stage – 2003 – when much, though not all of the market-making activities had taken place.

Insert Table 1 about here

An important distinction in our research is between these *emergent competitors* (i.e. directly-competing stent producers) and *established actors* (i.e. wider market actors such as coronary surgeons, hospitals and regulatory authorities). The emergent competitors all built on the work of technological advocates (doctors, engineers, entrepreneurs) who persisted – over several decades (see Fig.1, below) – in their determination to introduce this product. Notable among these advocates were Dr. Werner Forssmann, who catheterized his own heart in 1929; Drs. Cournand and Richards, who used cardiac catheterization as a diagnostic tool in the US for the first time in 1941; Dr. Charles Dotter, who, in 1964, performed the first 'transluminal angioplasty' (a less-invasive way of clearing blocked arteries using catheters, balloons and, later, stents); and Dr. Andreas Gruentzig, who in 1973 used a balloon for the first time to dilate human arteries, and who, in 1977, performed the same operation in a human coronary artery (with Hannah and Myler). Peripheral stents (those used to clear arteries in limbs) were developed in the 1980s, while J&J launched the first coronary stent in the US in 1994, which was followed by competing coronary stents in 1997.

Insert Figure 1 about here

In many cases, these coronary stents obviated the need for coronary artery bypass grafts (CABG – 'heart bypasses'), and from 1995 onwards, although the CABG market continued to expand, the number of stent insertions (or 'percutaneous trans-luminal coronary angioplasties' – PTCA) per CABG also began to increase. The potential disruption to the existing CABG market in this period is clearly illustrated in Fig. 2 below. J&J subsequently launched the first drug-eluting coronary stent (DES) in the US in 2003. DESs were introduced to limit a difficulty called 'restenosis' which describes a negative reaction that may occur, in some cases, following a bare-metal stent (BMS) insertion procedure. J&J held a monopoly position for approximately one year before competitors arrived into the DES market.

Insert Figure 2 about here

By 2006, approximately 1.2 million stents were used annually in the US, with 652,000 angioplasties being performed – each of them requiring an average of 1.84 stents. These stents were a mixture of bare-metal and drug-eluting models and cost from less than $1,000, up to in excess of $3,000 each, implying a US stent market of more than $3 billion that year. It is against this background of market development, technological progress and industry growth that this case is examined.

Analytical Frame

The primary focus of this research is on the dynamics involved in the emergence of a new market. In that sense there are three time periods of concern: pre-market; new market, and established market. Within these three time periods, we have identified four market 'moments'. The dynamics associated with the first of these – the pre-market phase – we will describe as *mutable marketing*. Our examination of the subsequent new market phase revealed two parallel sets of market–making processes occurring during this period. The first was between the emergent competitors, which we describe as *internecine marketing* due to its mutually aggressive nature. The second was between emergent competitors and established actors such as regulatory authorities, surgeons, patent offices, and so forth. We introduce the term *subversive marketing* to describe these dynamics as they tend to be far more subtle and diplomatic than those experienced between emergent competitors. We describe our fourth market moment – that which represents what might be referred to as 'normal' or 'stable' marketing behaviour – as *civilised marketing*. An analytical framework involving these concepts is presented below in Table 2. Each of these moments will now be discussed.

Insert Table 2 about here

Mutable Marketing

What distinguishes the mutable marketing moment is that, while market entities such as products, producers and consumers can be identified, at least retrospectively, *no market exists at this time*, meaning that economic activity, as usually understood, does not take place during this period. A market requires rules, material artefacts, calculative devices, governance structures, and agreed understandings of what constitutes a traded object (Rosa et al, 1999; Finch and Geiger, 2011), a buyer, a seller and the like. All of these 'come to be' during the market-making moment (Callon 1998, Araujo 2007). The term 'mutable marketing' is not used to suggest that something that might be described as 'real' marketing only begins when this phase is complete. Rather, it captures the idea that the prospective product associated with the market-that-might-come-to-be is under-developed, the actions that will come to be seen as market-making are unrelated, and the actors that will come to be seen as producers and consumers are only vaguely formed at this stage. Mutable marketing carries the sense that these entities are as yet unrevealed and the 'marketing' activities are perhaps only understood as such retrospectively. During the mutable marketing moment, product advocates begin to perceive each other as potential future competing producers. But before competition begins they absorb ideas, observe what product applications appear attractive, and consider potential opportunities. For example, Dotter's 1964 operation was imitated by Porstmann, Van Andel and Zeitler in Europe. Zeitler passed on the angioplasty technique to Gruentzig, who substantially developed it. Product advocates behaved similarly in business. Bill Cook (Cook Inc.), Hugo Schneider (Schneider Inc.), John Abele (Boston Scientific) and Dick Myler (cardiologist) all met each other at trade fairs from the late 1960s and through the 1970s, which they attended both to promote their own innovations and to observe each other's. Alliances and potential market opportunities were considered and formulated between these actors. In this phase these potential future competitors remained aware and tolerant of each other.

During this mutable marketing moment, the product remains exciting and new. The primary challenge its advocates face is to prove that it works, rather than to compete with other producers. The product moves from being entirely speculative to being proven in at least a single application. This product-proving requirement leads to some interesting recklessness on the part of the producers. For example, until 1929 it was thought that positioning a catheter in the human heart would be fatal. That year, Forssmann, refused permission to catheterise his own heart, induced a nurse to help him do so – then X-rayed himself to prove the catheter's location (Kerridge, 2003). He lost his job because of this recklessness, but subsequently shared the 1956 Nobel Prize for medicine for his efforts.

In less reckless circumstances – but still experimental – Cournand and Richards used catheterization for the first time in a diagnostic capacity in the US in 1941, while in 1964 Dotter used catheters as an interventional tool for the first time, to save the foot of an 82 year old woman from amputation. By 1969 Dotter was experimenting with stents in dogs' arteries, while others were experimenting with balloon dilation of human arteries. In 1977, the first human coronary angioplasty was performed by a team including Dr. Gruentzig.

It is feasible to believe that this recklessness was tolerated because the market remained so ill-defined and tentative. In an environment lacking in appropriate tools and infrastructure even the most ethical and best-prepared producers must sometimes work with products barely sufficient to the circumstances. However, although these applications represent technological progress, the product remains unrevealed during this moment. The product is not established, consumers are not widely aware of it, and even emergent competitors remain unclear about its eventual scope and capabilities. Callon (1991, 1998) speaks of 'immutable mobiles' as those products that have been black-boxed, or have been stabilized and are capable of being traded. Finch and Geiger (2011) reference 'cool' objects (Law and Singleton, 2005) and 'objects as black boxes' (Latour, 1987) in a similar context. Our mutable marketing moment describes a phase prior to this stabilization, when the product remains 'mutable', and the activities – what

Harrison and Kjellberg (2010) describe as 'investments' – required to make it immutable, are still being made.

While the investments Harrison and Kjellberg speak of are in market segmentation, the investments made by market actors in this case relate to the slow and gradual stabilization of a product so that it can be traded. These investments included Forsmann's self-catheterisation in 1929, the seventeen papers Dotter wrote in the four years after he pioneered the angioplasty process in 1964, the American Heart Association meetings that Gruentzig presented at – to lukewarm responses – and the clinic he opened in Zurich in 1978 in which he trained doctors from around the world, until in 1980 he was appointed Director of Interventional Cardiology at a major teaching hospital in the US where he carried on his product advocacy work.

These were investments made by medical professionals, but parallel investments were being made by business entities. John Abele and Peter Nicholas of Boston Scientific, and others, attended many trade fairs, promoting the technology and networking. Meetings frequently occurred between Abele, Cook, Schneider and other advocates, both in the US and Europe. These commercial entities developed many ways of promoting the technology including building briefcase-sized models of the human vascular system for demonstration purposes. For Abele, these investments included once lecturing Harvard medical students on the PTCA method.

These mutable marketing activities are important, because they help describe how the market comes to be. In the stent market these activities occurred over decades, until in 1994 the first coronary stent was launched in the USA. This is the point, we suggest, that the product stabilized and became capable of being traded. Subsequently, different market 'moments' occurred.

Internecine Marketing

Internecine marketing describes how emergent competitors interact with each other in an emerging market, as distinct from how they interact with established actors. In the stent case these relationships are

revealed as dramatically distinctive, with the emergent competitors exhibiting ruthless antagonism between themselves.

Following J&J's launch of the coronary stent in the US in 1994, Boston Scientific entered a 10 year, exclusive, worldwide licensing agreement with the Israeli stent manufacturer, Medinol, in 1995. In 1997, Boston Scientific began covertly developing its own abilities to produce Medinol's 'NIR' stents outside of these licensing terms. Medinol subsequently sued Boston Scientific for breaching agreements, misappropriating intellectual property and fraudulently filing documents with the FDA[1] in order to steal Medinol's business and conceal the scheme. In 2000, Boston Scientific conceded the existence of its reverse-engineered secret production line in Dublin, Ireland, claiming it was necessary because Medinol was such an unreliable supplier. At the same time, James Tobin, Boston Scientific's new CEO, stated that he was unaware he was involved with 'such crooks' and that he was 'ashamed to represent such a dishonest company'[2]. Following years of legal wrangling, Boston Scientific settled with Medinol in 2005, for $750 million. This activity is quite distinct from the strategic aspects of licensing examined in the literature (Brockhoff et al, 1999; Kollmer and Dowling, 2004).

As Boston Scientific was building the secret line to produce NIR stents outside its licensing terms, it also signed a co-exclusive agreement with Angiotech, to use 'Paclitaxel', a promising drug in the battle against restenosis. This was part of their development of drug-eluting stents. Cook, another emergent competitor, was the other 'co-exclusive' signatory to the agreement.

In 2001, Guidant, also wishing to develop a drug-eluting stent, signed an agreement with Cook to access Paclitaxel through that firm. This agreement was described by one judge in a resulting court case – initiated by Boston Scientific – as a 'sham'[3]. Following this judgement, which restrained Guidant from accessing Paclitaxel through Cook, Guidant moved to acquire Cook. In 2002, a subsequent judgement

[1] http://sec.edgar-online.com/boston-scientific-corp/8-k-current-report-filing/2001/05/01/Section5.aspx (accessed 13/4/12)

[2] *ibid*

[3] http://www2.indystar.com/library/factfiles/business/companies/guidant/stories/2002_0803.html (accessed

prevented Guidant from benefiting from work done with Paclitaxel during the period of the previous 'sham' agreement, even after Cook was acquired by Guidant. Guidant appealed, lost and, in 2003, withdrew from the acquisition, citing poor clinical trial results for a Cook stent as the reason. Table 3, below, provides a detailed summary of the associated clinical trials and the timing of the related actions.

Insert Table 3 about here

Guidant was subsequently (2006) acquired by, and split between, Boston Scientific and Abbott Labs following an aggressive bidding war with J&J. The ruthlessness required to engage in the fraud Boston Scientific was charged with, and to pursue access to complimentary technologies in the way that Guidant did, is driven by the need to acquire new product technologies. The drive to acquire these technologies means that firms engage in acquisition drives which are intense and sustained. A summary of the 'relationships' (acquisitions, alliances, licensing agreements, etc.) entered into by the dominant competitors during the internecine marketing phase is presented below (see Fig. 3). This pattern of ruthless acquisition partly defines how producers in emerging markets compete with each other.

Insert Figure 3 about here

The remarkable extent and scale of legal activities within the internecine marketing moment requires further examination as these sorts of activities – firms being sued for theft of technology, agreements being described by judges as shams, and ruthlessly acquisitive disputes – are not characteristic of competition in established industries. A diagram of some of the primary legal actions (not exhaustive) for the stent market during this phase is provided below (see Fig. 4). These legal actions are charted from 1997 – the time the first competitor to J&J's coronary stent is launched in the US – until 2005.

13/4/12); http://www.leagle.com/xmlResult.aspx?xmldoc=20021082208FSupp2d874_1978.xml (accessed 13/4/12)

Insert Figure 4 about here

The frequency with which emergent competitors sue each other, the repetitive nature of many of these suits, the propensity firms have for suing more than one producer for similar alleged infractions, and the strong likelihood that an appeal will immediately follow a negative outcome are revealed as characteristic of the stent market. This indicates that legal activity, in addition to being a principled response to infringements, is also a market-making lever of significant power. Prime evidence of this was provided by the district court of The Hague in Holland, which in 2004 delivered the first ever 'anti-suit' injunction in Dutch legal history. This injunction restrained Medinol from repeatedly suing other producers – on the basis of overlapping patents – with respect to issues that had already been decided. The decision indicated that 'when a party indulges in activity which can be characterised as an abuse of process, the court will take firm action.'[4]

Litigation between emerging competitors in the stent market was not confined to these difficulties. For years, producers sued each other repeatedly. In November 2000, subsequent to a 1997 lawsuit, Medtronic was ordered to pay J&J $271 million in damages for patent infringements. That December, Boston Scientific was ordered to pay J&J $324 million, also for patent infringements. Both of these orders were immediately appealed, and in March 2002, the Medtronic penalty was overturned and the Boston Scientific payment was set aside. Appeals and hearings followed in both cases. In March 2005, J&J won both cases, again, only to have Medtronic and Boston Scientific appeal – again. In January 2008, the courts heard the appeals and found in favour of J&J. This resulted in judgements against Medtronic and Boston Scientific in October 2008 of $521 million and $703 million, respectively. In June 2005, J&J had a different patent infringement suit against Boston Scientific judged in their favour, to the value of $844 million. This was countered by Boston Scientific's successful June lawsuit against J&J in Holland,

through which the firm hoped to stifle European distribution of J&J stents (Holland being the European manufacturing site for J&J at the time). In addition, a subsequent (US) judgement in July 2005 found that J&J stents infringed Boston Scientific patents.

In many cases, individual judgements are used as opportunities to conclude a wider set of actions. For example, in February 2002, Boston Scientific sued Medtronic in Germany claiming that the firm's 'rapid exchange' stent delivery system infringed its patents. In June, the German court agreed. In September that year, this case, and a range of other lawsuits between the two firms were settled following a $175 million damages payment from Medtronic. As part of the agreement, other stent products were cross-licensed between the firms, including abdominal aortic aneurysm repair and catheter manufacturing technologies. This is one means by which emergent competitors and established actors within the market are translated.

This series of lawsuits, appeals, counter- appeals and large penalties illustrates the ruthless and extensive nature of legal actions between producers. In the period from 1994 to 2005, there were repeated legal jousts between firms, with several judgements, arbitration outcomes and settlements arrived at each year. The intensity and frequency of these legal battles is not experienced in more established industries and is characteristic of internecine marketing dynamics.

These legal activities occur only between emergent competitors, and are not characteristic of the relationships between producers and consumers or other market entities. They occur after the emergent competitors have begun establish themselves and they represent an important aspect of the character of emerging markets. The legal dynamics between emergent competitors escalate in a way reminiscent of Rene Girard's idea that an actor not only wants to be like another (the model), but also wants what the model has (Desmond and Kavanagh, 2003). This leads to the development of 'doubles', who suffer 'an intolerable sameness' (Desmond and Kavanagh, 2003, p241), and thus become violently and mutually

[4] See: http://www.internationallawoffice.com/Newsletters/Detail.aspx?r=9041 (accessed 13/4/12); http://archive.epo.org/epo/pubs/oj005/05_05/05_sup.pdf (p.190) (accessed 13/4/12)

antagonistic to each other. These actors use the legal system as one of their most effective and frequently employed market-making levers, ruthlessly suing each other in the hope of destroying competing producers, delaying emergent competitors' product launches, or extracting large settlements. This ruthless and extensive legal activity is a dominant form of market-making engaged in by emergent competitors. And it is market-making in the most fundamental sense: emergent competitors are forming the structure of the market (who and what is in it), rather than seeking competitive advantage within an *already formed* market (using price competition, for example).

From a slightly different perspective, Schumpeter (1942/1976), Porter (1979, 1983), Rosenbloom (1985), Bower and Christensen (1995) and other contributors agree that there is a uniquely competitive process associated with the introduction of new products. These legal activities are part of that unique character. Afterwards, when the market has been translated into something new – when it has become civilised – these legal activities are substantially less in evidence. But at this moment – on the cusp of what Christensen (1997) might describe as the point of disruption – they are fundamental to the dynamics of the marketization process.

Subversive Marketing

The relationship between emergent competitors and established actors is far more subtle and emollient than the ruthless antagonism exhibited between emergent competitors. The challenge faced by producers could be interpreted as how to establish a market without aggravating established actors. Christensen and Raynor proposed that producers seeking to gain market share should 'compete against non-consumption' (Christensen and Raynor, 2003, p.45), or enter parts of a market that are not currently being served by existing actors. Clearly the distinction between establishing a new market and entering neglected areas of existing markets is a fine one. We suggest that emergent competitors attempt to advocate their products, while appearing deferential to established actors.

The move by the stent product from peripheral (e.g. unblocking arteries in legs) applications, through diagnostic, then interventional uses by radiologists, until finally, it began to displace a proportion of

CABG procedures, illustrates the central dynamic of the subversive marketing moment. We suggested earlier that an established market existed around the CABG product. This product was 'threatened' to some degree by the emergence of the stent product because some consumers chose the stent over CABG. But the stent product didn't merely *diffuse* (Rogers, 1962/1995; Dopson, 2005) within this existing market; rather it *translated* (Latour, 1991) the market by becoming more useful for a particular set of symptoms than CABG, and also by becoming established as a treatment for symptoms and applications to which CABG had never been suited. This meant that coronary surgeons, established actors in the CABG market, were unable to unilaterally prevent the emergence of this new product.

This instance describes an example of how initially the product is applied to one small, unimportant application (e.g. peripheral angioplasty), and because its encroachment into the nearest existing market is thus contained, it is tolerated by established actors who benefit from the acceptance of an existing product (e.g. CABG). The difficulty facing these established actors is that, as the new product broadens its appeal and range of applications – as it translates both itself and its market – it becomes more established and more difficult to suppress.

However, some restraining of the new product is evident in legal and quasi-legal activities between established actors – such as regulatory agents or patent offices – and emergent competitors. For example, in 1992 Boston Scientific and Hewlett-Packard entered an alliance to develop the technology that would become known as 'IVUS' (intravascular ultrasound) – a product useful for positioning stents. In 1995, Boston Scientific acquired another emergent competitor that was developing that product, only to be restrained from completing the deal by the US Federal Trade Commission. Boston Scientific executives felt that Hewlett-Packard had pressured the Commission to intervene. One senior Boston Scientific employee characterized the relationship by suggesting: 'Little did we know that Hewlett-Packard had such phenomenal clout in DC. They were behind the scenes, really leveraging.' (Rodengen, 2001, pp.164-5). The deal subsequently went ahead on the condition that some of the IVUS technologies were licensed to Hewlett-Packard. By regulating the degree of control Boston Scientific had over the IVUS

product and ensuring that at least two emergent competitors had access to it, this interaction further translated both the producers and the emerging market in which they were operating.

But, while contentious at the time, this could be perceived as part of routine regulatory activities. Product-specific legal interactions between emergent competitors and established actors take the form of regulatory control. This regulatory control frequently results from the conflict between the drive for market share – which producers experience in order to establish their products as de facto standards (Jakobs, 2005; Wonglimpiyarat, 2005) or dominant designs (Tushman and Anderson, 1990) – and the need for consumers and wider market actors, in contrast, to restrain this drive in order to maintain pre-existing markets, meet health and safety regulations, maintain intellectual property rights, and so forth.

An example of this process relates to the introduction of DESs in the US from 2003 into 2004. During 2003, rumours regarding difficulties with Cypher (J&J drug-eluting stent) insertions began to circulate, and from 2003 into 2004, J&J engaged in a protracted battle with the FDA, much of it in public, attempting to limit the impact of the controversy on Cypher sales. There were suggestions that the stents were causing blood clots to form, leading to heart attacks in the affected patients. The FDA became involved and claimed to know of 34 cases of such clots forming, and 5 deaths occurring[5]. They stated that the deaths were not necessarily linked to the clots. J&J and the FDA publicly agreed that the clots might not be more frequently encountered than they were with bare metal stents (there were more than 50,000 implanted Cypher stents at that stage) and that if they were, then the difficulty may have been more to do with insertion procedures and post-operative treatments than with the stent design. This reveals that it was the challenges associated with stabilising the new DES product within existing market practices that were causing problems. If DESs (such as the Cypher) had been the established product, then the insertion procedures and post-operative treatments would have been tailored to them, and it was the speed of translation of these procedures and treatments, to a regime sympathetic to Cypher use, that J&J needed to address, while fending off allegations that the Cypher was deficient in some fundamental

[5] http://www.oshmanlaw.com/pharmaceutical_litigation/heart_stents.html (accessed 13/04/12)

aspect. This translation was difficult for J&J to manage, as neither the firm nor the FDA could control how the device was used.

In terms of the argument between 'diffusion' and 'translation', this example illustrates how diffusion is a relatively static concept. Translation, in contrast, allows emergent competitors to perceive a period during which changes – within the broader market, and not directly controllable – will have to be made in order for its product to become immutable. Awareness of this phenomenon better equips producers to face the challenges associated with new market emergence.

Regulatory control is perhaps the dominant response of established actors to these market-making activities. The engaged reaction by emergent competitors to this regulatory response contrasts sharply with the parallel internecine marketing that occurs *between* the emergent competitors. The latter is impetuously antagonistic – violent in every sense except for the most literal, while the former is emollient, diplomatic, considered. We propose that there is a tension between these two marketing moments, which eventually leads to a more 'civilised' marketing moment.

Civilized Marketing

The civilized marketing moment describes a set of marketing dynamics within established markets that echoes Hirschman's doux-commerce ('sweet commerce') thesis wherein 'commerce [is] a civilizing agent of considerable power and range' (Hirschman, 1982, p1464). So, for example, while some price competition may be present, aggressive actions – those destructive to the mutually satisfactory circumstances – are rare. We describe this marketing moment as *civilized* in the sense that Elias used the term (see Elias and Jephcott, 1994/2000). Elias proposed that society comprises a set of interdependency networks, which are configured in certain ways at certain times. He suggested that changes occur to these configurations over time, as a result of the activities of the actors within these networks. These activities are influenced by the context within which the network is operating, the circumstances within which the individual actors find themselves, and their relative positions to each other. Asymmetries in power between these actors are important, as is the recognition that outcomes of actors' activities may not be as

planned. Elias's theory of civilization suggests that actors, who start out as impulsively violent in a relatively unstructured environment, become diplomatic, self-restrained actors over time, as the environment becomes more structured.

This move is mirrored in the stent market as the relatively isolated emergent competitors – acting impulsively and violently – become progressively engaged in a more complex interdependency network, involving existing customers, regulatory agencies, distribution channels, and so forth. This figurational change leads to a more 'civilised' market, within which established actors (previously emergent competitors) compete using conventional and well-understood tactics (e.g. price competition), in the absence of mutually-destructive market-making activities (e.g. repeated, overlapping lawsuits), in order to supply a well-understood and accepted product (until recently an emerging product).

The move to civilized marketing is a gradual change driven by two factors. The first is that a more refined 'agreement on a set of core elements that define the concept' (Rosa et al, 1999) comes into being between actors. At this stage, radical product development is no longer required, ownership of the product technology has largely been settled, and any incumbent product has been overcome to the extent that it will be. The new product has passed from being a potential solution, through being an alternative solution (to an existing one), to being *the* solution to a defined problem in a defined market – it has become 'blackboxed'. This term is used by Callon to describe how, as the product becomes more involved within a complex interdependency network – as it becomes more accepted and suited to the translated environment – it eventually becomes 'a single point or node in another network' (Callon, 1991, p.153). This node is the 'black box', the contents of which are accepted and which do not need to be reconsidered, and which can become a stable, reliable node in another, larger network. There is, in effect, less arguing to do, and that which remains revolves around 'civilized' marketing issues, primarily price and quantity.

The second way in which market actors are drawn away from their violently impulsive selves is through a growing awareness that it is difficult to determine the effect of any action they might take, or even to

select the 'right' action. It may well be that every emergent competitor wants to win the next court case, but they are wary of 'winning' the race to produce the first/best radioactive stent (a 'losing' product). In addition to fitting into Elias' perspective, this dynamic relates closely to Fligstein's (1996) view that 'no actor can determine which behaviours will maximize profits… and action is then directed towards the creation of stable worlds' (Fligstein, 1996, p659). This growing restraint is augmented by the developing differences between emergent competitors. Some, through a combination of incremental sales increases, acquisitions and technological improvements, have become larger and stronger. These asymmetries in power lead smaller producers to become more deferential towards larger ones, and the bigger producers' norms increasingly become market norms. In short, the market becomes established.

In Schumpeterian terms, the supermarkets have taken over completely from the corner stores, and are now exhibiting the same 'normal' competitive activities as the corner stores did before them. Unless some new element is injected into the competitive arena, none of the competitors will break the rules. Detergent manufacturers will compete on cost, product placement and advertising; department stores will compete on price, and on the range and novelty of their wares. A serious attempt by one producer to exclude another from the market would be exceptional. For the same reasons, legal actions are rarely employed once the civilized marketing moment comes into being.

Discussion and Conclusions

This research leads to three broader conclusions which we now highlight. Our first conclusion is that emergent competitors operate clearly different strategies with respect to directly competing producers and established actors in emerging markets. This conclusion is useful in two regards: it illuminates the market-making dynamics between emergent competitors, and it distinguishes these dynamics from those between emergent competitors and established actors. This contrasts with much of the literature which has focused heavily on the reaction of established actors to the threats presented by emergent competitors (e.g. Cooper and Schendel, 1976; Clemons et al, 1996; Gans et al , 2002; Rothaermel, 2001; Howells, 2002; Hill and Rothaermel, 2003) and which has produced terms of such popularity – 'creative

destruction'; 'disruptive technology' (Schumpeter, 1942/1976; Ehrnberg, 1995; Christensen 1997; Henderson, 2006) – that they may be limiting further insights into this area rather than facilitating them.

Our second conclusion is that legal activities are dramatically more important in market-making dynamics than was previously thought. The range and scale of legal activities are impressive in themselves, but it is the contrast between their *nature* and that of 'normal' legal actions which is fundamental to understanding their importance. Although research into the legal issues surrounding new products is not uncommon, it tends to focus on patenting and associated issues (e.g. Archibugi and Pianta, 1996; Brockhoff et al, 1999; Maklem, 2005; Pilkington and Dyerson, 2006) rather than on the utilisation of legal methods as front-line market-making levers.

Our research reveals that legal activities between emergent competitors are ruthless and extensive, with a series of repeated and overlapping lawsuits, often closely connected to related issues. The resolution of these issues frequently presents an opportunity to resolve a wider set of actions between producers, and signals a lull in the legal activities for some months before they are re-activated.

Legal actions also occur between emergent competitors and established actors, but its nature is quite distinct to that exhibited between producers. In this case, the legal activity takes the form of a sort of regulatory restraint applied by established actors to the drive by emergent competitors to achieve market share. Both of these patterns of legal activity represent major marketization dynamics within emerging markets.

Market-making is dynamic in nature – a recognition fundamental to this work – and without the longitudinal nature of this research, these dynamics could not have been revealed. Actor network theory considers change (e.g. the introduction of a new product) as a process of translation, and with *process* in mind, we would add a third conclusion. If what Schumpeter described as 'creative destruction' defines the overwhelming of an old product by a new, then the process of transforming the identities of a new product, and those who encounter it, during its emergence, is quite distinct. This process – which we will

describe as 'creative *con*struction' – encompasses the emergence and gradual acceptance of the new product.

Our distinction of this process from Schumpeter's echoes our earlier contrast between the literature's focus on the reaction of established actors to emergent competitors, rather than the marketization dynamics between emergent competitors. If 'creative destruction' represents the process of translating *from* the point of disruption to the point where the new product becomes dominant, then 'creative construction' represents the process of translation evident *at* the point of disruption, with the new product coming into being. We're making this point because, just as it is more interesting to examine the relationships between actors than the actors themselves, we feel it is important to examine the nature of change between states – i.e. at the point of disruption – rather than the distinctive states evident either prior to or following the change. Introducing the concept of creative construction and distinguishing it from creative destruction may help to refine the use of the latter term and to further clarify the issues surrounding market-making dynamics at the point of disruption.

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Firm	Boston Scientific	Guidant	J&J/Cordis	Medtronic AVE	Abbott Labs (Abbott Vascular Devices)
Founded	1979	1994	1887 (J&J), 1959 (Cordis)	1949 (Medtronic), 1991 (AVE)	1888 (Abbott Labs, 1984 Biocompatibles
Founder	John Abele, Peter Nicholas.	Eli Lilly spin-off.	Robert, James and Edward Johnson (J&J)	Earl Bakken, Palmer Hermundslie.	Dr. Wallace Calvin Abbott. Prof. Dennis Chapman (Biocompatibles)
HQ	Natick, Massachusetts	Indianapolis	New Jersey (J&J), Miami (Cordis)	Minneapolis	Chicago
Activities	Less invasive medical devices.	Cardiovascular medical products.	Less invasive treatment of vascular disease. (Cordis)	Treatment of chronic disease especially heart disease.	Global pharmaceuticals, nutritionals, and medical products, incl. diagnostics and cardiovascular devices.
Divisions	Two operating groups (Cardiovascular and Endosurgery) marketed through 6 divisions. EP Technologies. Medi-tech. Scimed. Target. Microvasive Endoscopy. Microvasive Urology.	Cardiac Rhythm Management. Vascular Intervention. Cardiac Surgery. Endovascular Solutions.	1. Cardiology 2. Endovascular 3. Neurovascular 4. Biosense Webster Inc. (Cordis)	1.Cardiac Rhythm Management 2.Cardiac Surgery 3.Vascular 4.Neurological and Diabetes 5.Spinal, ENT and SNT	Two operating groups (Pharmaceutical Products and Medical Products) the former marketed through several divisions including Ross Products and Abbott International, the latter through several divisions including Abbott Diagnostics and Abbott Vascular Devices.
Employee Numbers	15,000	12,000+	5,300 (Cordis) 110,000 (J&J)	32,000 (Medtronic)	55,000+ (Abbott Labs)
Sites	'Represented in 40+countries worldwide.	19	57 countries	Worldwide	120 worldwide
Market Focus	Global	Global	175countries+ worldwide	120+ countries worldwide	130+ countries worldwide
Total Assets	$5.7B	$4.64B	$48.26B (J&J)	$12.32B (Medtronic)	$26.72B (Abbott Labs)
Revenue	$3.48B	$3.7B	$14.9B (J&J 'Medical Devices and Diagnostics') $41.86B (J&J)	$7.665B (Medtronic)	$19.7B (Abbott Labs) $185 million (AVD)
R&D Expenses	$452M (12.98%)	$518M (14.00%)	$4,684M (11.18%) (J&J)	$749M (9.77%)	$1,733M (8.79%) (Abbott Labs)

Table1: Dominant Stent Market Competitors (2003)

	Product	Legal	Relationships	Market
Mutable Marketing	Exciting and new. Proving ground. Single application.	Non-issue.	Personal, tolerance between a few, influential actors.	Vague, tentative 'market'. Emergent competitors unfocused. Regulatory issues unclear.
Internecine Marketing	Established as viable.	Super-aggressive lever, not just principled response of last resort to infringements.	Mutually antagonistic creation of doubles.	Acquisition feeding frenzy. Products and producers targeted.
Subversive Marketing	Ongoing market translation activities.	Regulatory restraint.	Deferential.	Swingeing market-share shifts. Different consumers and product applications.
Civilized Marketing	Standardised, commoditized, trusted in an application, black-boxed, punctualised.	Infrequent, exceptional.	Stable.	Established. Large producers identified with product. Slow expansion of market.

Table 2: Analytical Frame

Date	Activity
1997	Angiotech signs co-exclusive agreement with Boston Scientific and Cook to develop Paclitaxel-coated devices.
November 2001	Guidant's 'Action' trial for Antinomycin-coated devices enrolled.
Autumn 2001	Cook and Guidant agree use of Paclitaxel.
Autumn 2001	Boston Scientific files for arbitration regarding Guidant/Cook agreement.
December 2001	Arbitration fails and dispute is transferred to court.
Early 2002	Cook 'Elutes' trial enrolled.
March 2002	'Action' trial cancelled.
March 2002	Guidant's 'Deliver' trial for Paclitaxel-coated devices enrolled.
June 2002	Cook/Guidant Paclitaxel agreement ruled against in court.
Summer 2002	Guidant bid to acquire Cook.
October 2002	Guidant legally restrained from using any benefit from previous Cook alliance. Guidant appeals.
November 2002	Guidant's appeal rejected.
January 2003	Guidant triggers 'get-out' clause in Cook acquisition.

Table 3: Guidant's drug-eluting stent activities

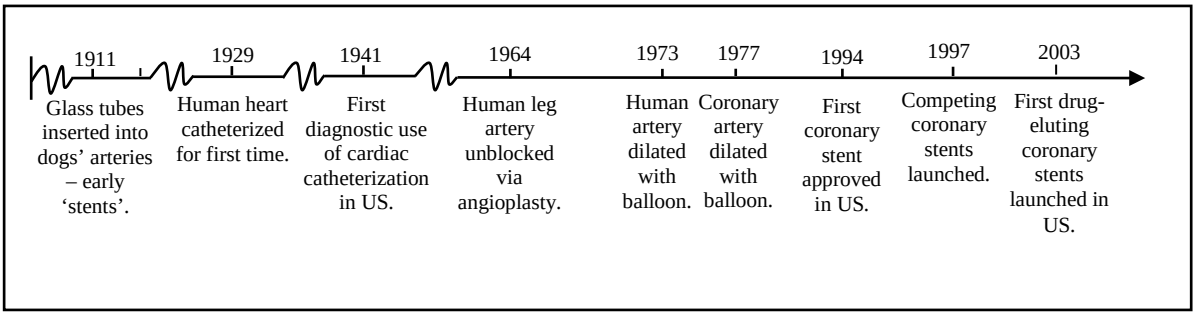


Figure 1: Emergence of Stent Product

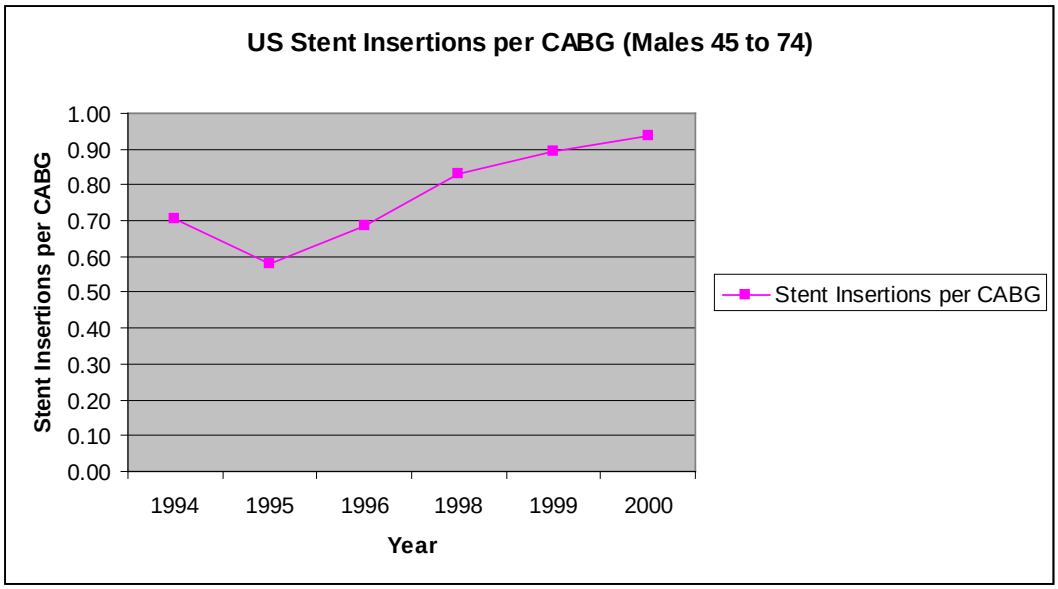


Figure 2: US PTCA vs. CABG Trends (Males per 100,000 of the population, 1994 - 2000)

(Adapted from http://www.cdc.gov/nchs/data/misc/healthcare.pdf)

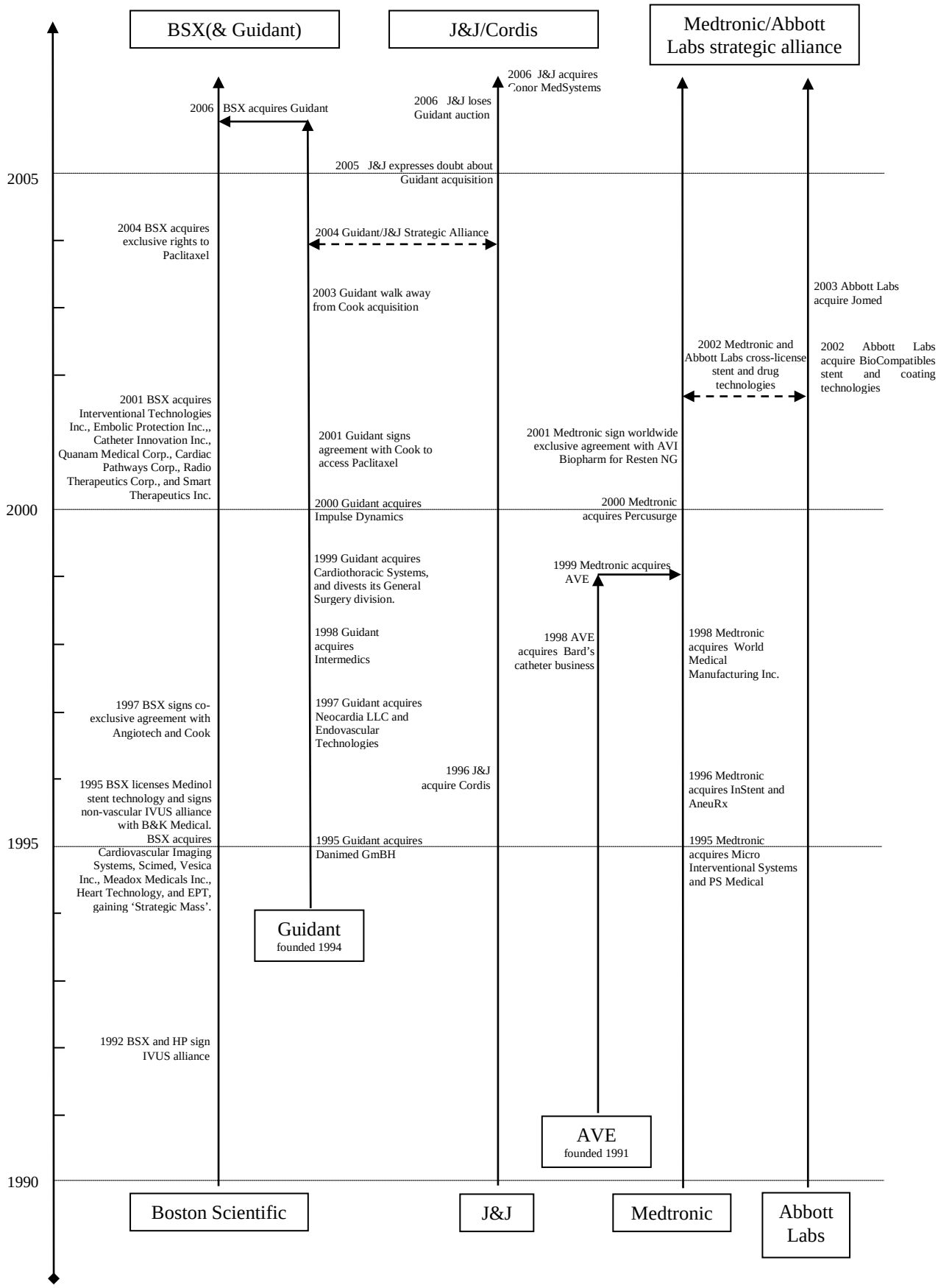

BSX(& Guidant)
J&J/Cordis
Medtronic/Abbott Labs strategic alliance
2006 BSX acquires Guidant
2006 J&J loses Guidant auction
2006 J&J acquires Conor MedSystems
2005
2005 J&J expresses doubt about Guidant acquisition
2004 BSX acquires exclusive rights to Paclitaxel
2004 Guidant/J&J Strategic Alliance
2003 Guidant walk away from Cook acquisition
2003 Abbott Labs acquire Jomed
2002 Medtronic and Abbott Labs cross-license stent and drug technologies
2002 Abbott Labs acquire BioCompatibles stent and coating technologies
2001 BSX acquires Interventional Technologies Inc., Embolic Protection Inc.,, Catheter Innovation Inc., Quanam Medical Corp., Cardiac Pathways Corp., Radio Therapeutics Corp., and Smart Therapeutics Inc.
2001 Guidant signs agreement with Cook to access Paclitaxel
2001 Medtronic sign worldwide exclusive agreement with AVI Biopharm for Resten NG
2000
2000 Guidant acquires Impulse Dynamics
2000 Medtronic acquires Percusurge
1999 Guidant acquires Cardiothoracic Systems, and divests its General Surgery division.
1999 Medtronic acquires AVE
1998 Guidant acquires Intermedics
1998 AVE acquires Bard's catheter business
1998 Medtronic acquires World Medical Manufacturing Inc.
1997 BSX signs co-exclusive agreement with Angiotech and Cook
1997 Guidant acquires Neocardia LLC and Endovascular Technologies
1996 J&J acquire Cordis
1996 Medtronic acquires InStent and AneuRx
1995 BSX licenses Medinol stent technology and signs non-vascular IVUS alliance with B&K Medical.
BSX acquires Cardiovascular Imaging Systems, Scimed, Vesica Inc., Meadox Medicals Inc., Heart Technology, and EPT, gaining 'Strategic Mass'.
1995
1995 Guidant acquires Danimed GmBH
1995 Medtronic acquires Micro Interventional Systems and PS Medical
Guidant
founded 1994
1992 BSX and HP sign IVUS alliance
AVE
founded 1991
1990
Boston Scientific
J&J
Medtronic
Abbott Labs

Figure 3: Producer Relationships during Internecine Marketing Moment

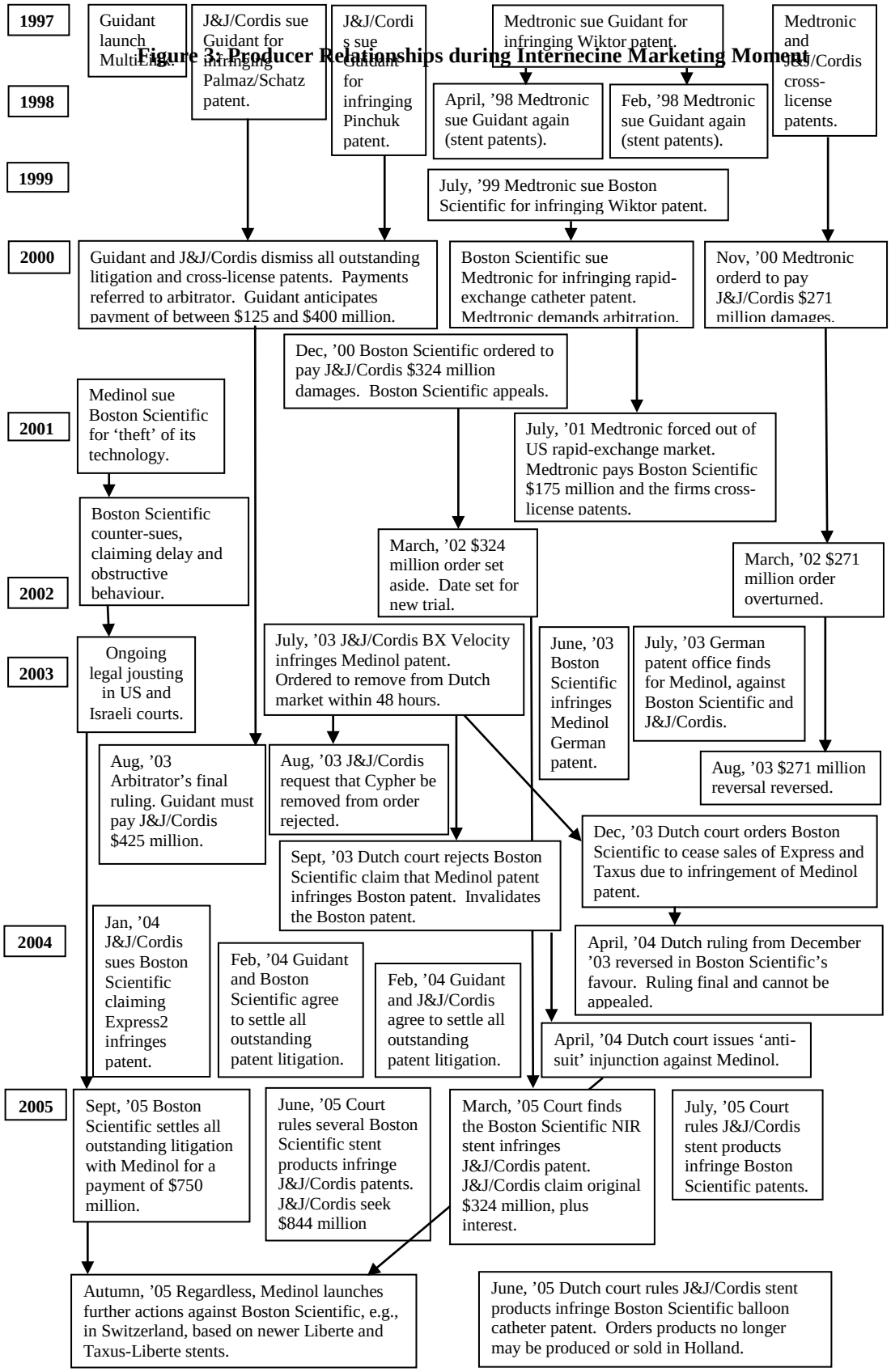


Figure 4: Legal Activities during Internecine Marketing Moment