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Regulating Disruptive Innovations: The Policy Disruption of Electronic Cigarettes

Jacob Hasselbalch

Erasmus Mundus Doctoral Fellow

University of Warwick & Université Libre de Bruxelles

E-mail: j.a.hasselbalch@warwick.ac.uk

Web: www.warwick.ac.uk/jhasselbalch

Abstract

This paper draws on the example of e-cigarette regulation in the European Union to introduce the concept of policy disruption. To do so, I make two analytical distinctions: first, between disruptive technologies and disruptive innovations, and second, between disruptive innovations and policy disruptions. Policy disruptions are the political fallout of disruptive innovations. They are caused by a deficit in regulatory capacity due to rapid increases in the rate of change in a regulated market. Not all disruptive innovations cause policy disruptions. Disruptive innovations that are fast-moving, novel and obscure allow disruptors to move before regulators, catching them off guard. When the innovations are controversial, they build political pressure. Due to technicality, complexity, and transnationality, policy disruptions are sustained and difficult to address. Policy disruptions can be adapted to by making regulation faster or making the market slower, and examples of this are provided. By revisiting the evidence, I argue that there is evidence that e-cigarettes have created a policy disruption in the EU.

Key words: disruptive innovation, electronic cigarettes, regulation, European Union, policy disruption

Introduction

In an excerpt from their 2013 annual report, Goldman Sachs identify eight disruptive themes. The excerpt, called “The Search for Creative Destruction”, refers to Schumpeter’s original coining of the term in 1942 and defines creative destruction as a process that is “driven by product or business model innovation – often abetted by technology – that results in a superior value offering for consumers, be it higher performance, greater convenience, or lower cost” (Boroujerdi 2014). The first of these disruptive themes are electronic cigarettes, or e-cigarettes, that have “the potential to transform the tobacco industry.” According to the excerpt, e-cigarettes are possibly more than 99% less harmful than normal cigarettes and offer an economic bargain as well. On August 7, 2013, Goldman Sachs predicted that e-cigarettes could grow to 10% of the total tobacco industry volume and 15% of the profit pool by 2020. These considerations make e-cigarettes a fast-growing and highly lucrative market. In the United Kingdom alone, the number of e-cigarette users has tripled from 700,000 in 2012 to 2.1 million in 2014 (ASH 2014). The global market for e-cigarettes and vaporizers grew from \$1.7 billion in 2013 to \$2.5 billion in 2014.¹ Initially pushed by small, independent enterprises, big tobacco companies have taken notice of the profits being made and are starting to buy up or enter the e-cigarette market. All the major labels now own e-cigarette ventures (Grana et al. 2014).

¹ See <http://online.wsj.com/articles/big-tobaccos-e-cig-push-gets-a-reality-check-1409078319>, accessed October 23, 2014

E-cigarettes are a disruptive innovation that have raised important regulatory concerns that have so far been very difficult to accommodate. The purpose of this paper is to rely on the example of e-cigarettes to make a distinction between disruptive technologies, disruptive innovation, and policy disruption. In doing so, I reflect on what it is that makes some innovations disruptive, what it means to be disruptive (and disruptive to whom?), and why disruptions are difficult to regulate. These reflections draw on literature from studies on management, innovation, science and technology, public policy, regulation and sociology. Engaging with the social and political ramifications of disruptive innovations such as e-cigarettes requires a truly interdisciplinary approach. In the remainder of this section I provide some background on e-cigarettes and the regulatory dilemmas they create.

E-cigarettes were invented by the Chinese pharmacist Hon Lik in the early 2000s (Grana et al. 2014). Also called personal vaporizers, they are devices that usually come in the form and size of a large pen. They contain a battery, a heating element and a nicotine-containing liquid solution. The solution is heated up to produce a mist or vapor rather than cigarette smoke. This produces the feel of smoking without the more harmful side effects of actually combusting tobacco leaves.. Because of this, e-cigarettes are an attractive alternative to smokers in search of healthier ways to enjoy their habit. Their appeal lies in being much closer to the sensation of regular smoking than other nicotine replacement products such as chewing gum, band-aids or snus. Thus, in addition to catching the interest of the big tobacco companies, pharmaceutical producers have also taken note of the possibility of using e-cigarettes as a smoking cessation tool. These characteristics, coupled with the growing social pressure on regular smoking, have paved the way for their rapid uptake.

The growing popularity of e-cigarettes has not been uncontroversial however. Fuelled by internet sales, the market developed and evolved so fast that regulators were forced into a reactionary role rather than steering. This led many people to describe the e-cigarette environment as a “regulatory Wild West”.² Others have described it as a new golden age for tobacco companies mirroring that of the 1950-60s, who suddenly find themselves with new products to advertise and sell with little to no restriction (Rudin & Alcock 2014). Worldwide regulatory answers vary from none at all to complete bans, but the tempo of the e-cigarette market has resulted in a policy environment that is itself evolving at an unprecedented rate. At the heart of the regulatory debate lies the question of how e-cigarettes relate to existing tobacco or pharmaceutical policies. What makes the regulatory debate very difficult to address is the fundamental uncertainty regarding their safety:

“Given how long it took to discover the link between smoking and lung cancer when the risks were so great, we have to accept that it will probably be more than 30 years before we would have a chance of being able to use epidemiology to quantify risks from e-cigarette use. In fact we may never be able to do so because we are *chasing a moving target* in terms of the products and their development.” (West & Brown, 2014, p. 442, emphasis added)

Without the assurance of epidemiology trials, public health professionals have to rely on toxicology tests to estimate the risks of e-cigarette use. While such tests agree that the toxicity of e-cigarettes is well below that of normal cigarettes (at about 1/20th of the level), toxicity tests do not provide the same level of certainty as epidemiology trials that involve a large number of participants over a longer span

² See e.g. <http://www.npr.org/2013/10/21/239269426/e-cigarettes-a-nearly-2bn-industry-a-regulatory-wild-west>, accessed October 24, 2014

of time. There could be other risk factors associated with the use of e-cigarettes that only become apparent over time or that are not covered by toxicology tests. Adding to the safety concerns is the wide variability in e-cigarette product engineering. Most of the devices are manufactured in mainland China, and studies have found variance in nicotine concentrations, volumes of solution, carrier compounds, additives, flavors, battery voltages and quality of manufacturing (Grana et al. 2014).

In addition to unknown long-term health impacts, three different social or behavioral effects are often raised as concerns. First, there is the concern that widespread use of e-cigarettes will re-normalize smoking. The prevalence of e-cigarettes could thus lead to an increase in smoking of normal cigarettes, or a slowing down of the rate of decline. Second, there is only limited evidence that e-cigarettes aid in smoking cessation. Most studies find that they are no more successful than other pharmaceutical quitting aids (West & Brown 2014). Third, some worry that e-cigarettes could function as a gateway drug – that is, leading previous non-smokers into smoking normal cigarettes. In all these concerns, the main obstacle to realizing certain answers is the novelty of e-cigarette use and the ongoing rapid evolution of the market. Long-term epidemiology trials will have to wait thirty years. The social and behavioral effects could be measured before then, but currently there is no consensus. Once more conclusive measurements start to materialize however, there is still the concern that such effects are contingent to specific cultural contexts and may not be generalizable.

All of this leaves regulators in a difficult position. Acting on the assumption that e-cigarettes will reduce the harms of smoking by serving either as a cessation tool or by replacing normal cigarettes, regulators are under pressure to set clear guidelines concerning their production,

distribution and consumption. Policymakers that care about public health are facing a dilemma: if they ban e-cigarettes, they could possibly forego a momentous opportunity to reduce the harm of smoking – but if they support e-cigarettes, they risk providing tobacco companies with new sources of revenue and re-normalizing smoking, as well as exposing users to unknown long-term risks. This strange double bind is summarized in the following quote:

“This brings us back to the question as to why some individuals and bodies involved in public health are so opposed to e-cigarettes. It may be a concern over how things might turn out in the future given commercial incentives, puritanical ethics, distaste for any industry profiting from a psychoactive drug, inappropriate application of a medical rather than a public health model, or even just a gut feeling that e-cigarettes are bad. Whatever the reasons, it is important that interpretation of the evidence and communication with policy makers and the public is not distorted by a priori judgements.” (West & Brown 2014, p.443)

What does objective, evidence-based policy look like when there is no scientific consensus? How can policymakers proceed without resorting to a priori value judgements in these cases? How do they determine their policy positions in complex and fast-changing fields that lack scientific consensus? Regulating e-cigarettes demands that we engage with these types of questions and pay attention to how practices constitute the policymaking process. Under conditions of complexity, interests emerge out of social interaction and do not determine it (Woll 2008). Ideas and discourse matter, but focusing solely on these blinds us to material conditions (Adler & Pouliot 2011) or the social relations and positions that make the recognition of expertise possible (Lazega 1992; Seabrooke 2014). Practices,

everyday performances of shared and contested knowledge, force us to engage with the relationships between structure and agency, materiality and discourse, and stability and change (Adler & Pouliot 2011, p.2). It is not a grand theory of the social, but it is a better way to approach areas of research where it is advisable to avoid any pre-social determination of interests or identities (Seabrooke & Tsingou 2009). It is therefore clear that this case study exposes more fundamental questions about modern notions and practices of policymaking under conditions of complexity, as well as questions about how these should be approached by researchers. These types of questions are especially brought forward by disruptive technologies and disruptive innovations, such as e-cigarettes. They are important to deal with because disruptions are often the cusp of wide-spread societal change, and their regulation will determine how risks and rewards are distributed across societal sub-groups. In the next section I clarify what is meant by disruptive technology and disruptive innovation. Following that, I identify and define the concept of policy disruption and show how e-cigarettes are an example of this. The final section reflects on how to study policy disruptions by drawing on insights from the regulatory debates concerning e-cigarettes.

Disruptive technology and disruptive innovation

The case example in the previous section illustrates the difference between disruptive technology and a disruptive innovation, and it implies a number of considerations about what it means to be disruptive. I situate this discussion in more recent literature on disruption, although the idea traces its intellectual heritage at least back to Schumpeter's (1942) "creative destruction", itself adapted from Marx. In the management literature, the term "disruptive technologies" originates in Bower &

Christensen's (1995) article in the Harvard Business Review: "Disruptive technologies: Catching the wave". Through a study of the computer disk drive industry in the 1980s, the authors make the distinction between sustaining technologies and disruptive technologies. Sustaining technologies are those that provide incremental improvements to product characteristics that are already valued by customers. Disruptive technologies, on the other hand, introduce a different package of product characteristics to the one valued by mainstream customers, and initially these products tend to perform worse on a few key dimensions. At the outset, therefore, they are offered in smaller niche markets, where their specific characteristics are especially valued. Over time however, the products that rely on disruptive technologies improve at a quicker rate than the sustaining technologies of a mainstream market. This results in a previous niche product suddenly becoming mainstream, when their value proposition exceeds that of earlier products. The example of the disk drive industry in the 1980s is telling: each time the diameter of disk drives shrank (from 14 inches to 8, then to 5.25, and finally to 3.5), the new technology was initially shunned by incumbents and left for new entrants to take advantage of until they dethroned the incumbents. In a series of follow-up books, Christensen and co-authors chart the same developments in a series of other industries and sectors (Christensen 1997; Christensen & Raynor 2003). Although the validity of the theory and its uncritical application to societal domains such as schools and hospitals has been criticized (Lepore 2014), disruptive innovation remains one of the most widely cited and influential ideas in modern business.

Christensen's analyses of disruptive innovation focuses on mutual cycles of readjustment between firms, competitors and customers. The role of the state goes unexamined in these accounts. In management and economics, the state is most often seen as getting in the way of innovation by

excessively regulating market activity, which it should only do when absolutely necessary to correct market failures (Williamson 1971). The strongest challenge to this notion of a passive state comes from Mazzucato's (2013) book *The Entrepreneurial State*. In this book she forcefully argues that the most dramatic innovations of our times, such as the Internet, could not have been accomplished without state involvement. She provides an illustrative example of the Apple iPhone in order to demonstrate that each of the core technologies that made the iPhone such a disruptive product have their origins in state-funded research programs, often with military uses in mind. While Christensen, Bower and Raynor are preoccupied with how disruptive technologies impact individual firms and industries, Mazzucato is more interested in where disruptive technologies originate, and how the public can benefit from a stronger role of the state in innovation systems.

Mazzucato admits, however, that while the core technologies of the iPhone have their origins in state-funded programs, it took the visionary design and marketing skills of Apple coupled with their efficient production and distribution channels to turn those technologies into a compelling product. There is thus a distinction to be made between *disruptive technologies* and *disruptive innovations*, which I define as follows: Disruptive technologies imply those technologies that present remarkably better or faster ways of accomplishing something. Disruptive innovations make use of disruptive technologies to present end-users with a product or service that is remarkably better than existing versions, thereby creating a new market or radically altering the terms of competition in existing ones (and often both). Innovations imply a market and a commercial motive, while technologies do not. Disruptive technologies and innovations can both come from either the public or private sectors. The iPhone example suggests that the state may be more likely to fund research that

results in disruptive technologies, which can become disruptive innovations when they are repackaged and sold to customers by companies. As an example, GPS (global positioning system) is a disruptive technology, while Google Maps is a disruptive innovation. Technologies are more neutral and can be repackaged to meet different needs – innovations equal this repackaging into actual products with well-defined value propositions. Another way to put it is that disruptive technologies are what make the product or service physically possible, while disruptive innovations ensure social appeal and economic viability. The distinction is semantic more than real, as it is often difficult in practice to draw the border between technology and innovation, but in the following I employ it as a heuristic device.

Disruptive innovations only become disruptive if they meet or create a demand. It is not enough to offer a compelling value proposition if there is no need or interest in it. There is thus a demand side of the equation in addition to the supply side discussed above. If states, universities and companies all play a role in the supply side of disruption, how can we conceptualize the demand side? Rao (2009) argues that radical innovations often flounder because their developers overlook the social and cultural mobilization needed to entice target customers into buying their product. Early adopters, what Rao calls market rebels, are instrumental in this regard.

Market rebels are more than early adopters of an innovation, however. Disruptive innovations, by their very nature, challenge the status quo in terms of interests, norms, values, practices and relationships. The social acceptance or rejection of an innovation is often dependent on the actions of activists who rely on 'hot causes' and 'cool mobilization' to organize their campaigns (Rao 2009). Hot

causes are those that inspire feelings of pride or anger, arouse to action, and create identity. In the early days of the personal computer, an example of a hot cause was the negative reaction against the tyranny of centralized computing. Cool mobilization is the generation of social experiences, communities of feeling, that create new behavior. Hobbyist computer clubs are an example of this. Together, hot causes and cool mobilization power collective action, and collective action creates or constrains markets. According to Rao, personal computers would have faced very different market conditions if it were not for the activities and campaigns of market rebels that convinced the public of the PC's benefits and drove social acceptance. Social rejection is equally important, as the case of the biotechnology industry in Germany shows. Activists reduced biotechnology to genetic engineering and connected it to Nazi eugenics programs. This forced German pharmaceuticals to abandon existing plants in Germany and move production abroad.

The idea of market rebels makes a broader point about disruptive innovation, namely: disruptive innovations do not occur in a social vacuum. Innovations are not judged solely on instrumental terms by objective arbitrators. They are subjected to social interpretation and construction. E-cigarettes can be seen as either quitting devices like nicotine chewing gum, a new revenue stream for big tobacco, a safe way to smoke that supports entrepreneurial SMEs, or as something else entirely. The underlying disruptive technologies and their repackaging into innovative products provide the raw materials of a disruption, but the battle to determine how the innovation is perceived is equally important. For an innovation to become truly disruptive – that is to bring about real market and societal changes – technologies, value propositions, and social understanding have to be in harmony. Perception partly depends on expectations about the future impact of the innovation.

Innovations are by definition new arrivals in society and markets, so extrapolating their current characteristics to future impacts is a key exercise in shaping perception (Beckert 2013). For these reasons, there is no ultimate yardstick of disruption, as it is inherently context-dependent and case-specific (Flyvbjerg 2001, pp.38–49).

There is no specific analytical or objective threshold at which something becomes disruptive. Rather, disruption is a characteristic that is both real and constructed (cf. scientific 'factishes', Latour 2010, pp.1–66). Innovations have to be perceived to be doing something better or different, and this is reflected in real market changes and real societal changes. For example, the e-cigarette disruption has led to the establishment of new firms selling new products that result in new social behavior, such as indoors vaping. While real changes are apparent to all, their meaning is subject to interpretation and contestation. Are indoors vapers patients using the newest nicotine replacement therapy to stop quitting, or are they re-normalizing smoking and making it culturally acceptable? The meaning of these changes are socially constructed, and the outcome of this construction has real consequences for the ongoing development of the market (Adler 1997).

How were e-cigarettes disruptive then? The underlying technologies of the e-cigarette are not particularly interesting in their own right (a battery, a heating element with a wick, and a nicotine-containing liquid solution). Combined, however, their economic and social value proposition is compelling. In terms of the distinction between disruptive technology and disruptive innovation developed above, the primary technological driver that made e-cigarettes feasible was battery miniaturization. Battery miniaturization on its own does not lead to innovative ways to smoke

however – the innovation of e-cigarettes was reliant on a concatenation of various factors: the demand for healthier alternatives, the increasing bans on smoking in public places, the economic feasibility of manufacturing e-cigarettes, and internet sales channels. The e-cigarette innovation presents smokers with an economic and health bargain that is incontrovertibly better than smoking regular cigarettes. They allowed a cottage industry to grow fast enough to gain the attention of the big incumbent tobacco companies. They have resulted in several hot causes (making smoking cool again, fighting big tobacco, public harm reduction from smoking) and cool mobilizations (trade associations, political movements, subcultures, blogs and do-it-yourself communities).³ According to the Goldman Sachs report alluded to earlier, the growth potential of the e-cigarette market is enormous, and public health experts have estimated that for every 1 million smokers in the United Kingdom that switch to e-cigarettes, 6000 premature deaths from smoking may be avoided each year (West & Brown 2014). If all of the UK's 9 million smokers switched, that would result in 54,000 premature deaths being avoided out of the 60,000 that would occur each year. Considering all of these features together leaves us with no option but to conclude that e-cigarettes are a truly disruptive innovation. Even with all of these stars aligned however, there is one aspect that will have a very strong influence on the future of the e-cigarette market: politics, and decisions about legality and regulation.

Bringing back politics

A crucial part of the social response to disruptive innovation finds its manifestation in the form of political deliberation and regulation. In analyzing the relationship between innovations and

³ See <http://www.theatlantic.com/health/archive/2014/10/the-right-to-vape/381145/>, accessed October 27, 2014

regulation, it is apparent that a great deal depends on whether the regulator or the innovator moves first, so to speak. Sequence matters (Abbott 1990). When regulators move first, they are in the steering seat guiding the evolution of a new market. Regulation can either foster or hinder access to an innovation, and it can set the terms of operation and competition in the market. Examples of this include the markets for medical drugs that have to be approved by regulators on the basis of medical trials. Another example is the solar panel industry in European countries that subsidized private installation costs, such as Denmark and Germany. These types of interactions are well understood in the literature, where many studies are preoccupied with how regulation and state involvement can boost innovation and hence competitiveness of national economies or regions. Examples include, but are not limited to, the systems of innovation literature (Freeman & Soete 1997; Mazzucato 2013) working primarily from a tradition of economics, or the institutional competitiveness literature in political science (Campbell & Pedersen 2007; Marcussen & Kaspersen 2007).

However, when the innovator moves first, regulators are forced into a reactionary role of controlling a market that has evolved entirely outside their auspices or restructuring existing markets that have been disrupted. Regulation as reaction to innovation is less studied in the literature. Within comparative political economy, Ornston (2012) studies how the Nordic states restructured when their traditional low- and medium-technology industries, on which their wealth was based, came under pressure due to technological disruption. He argues that a specific Nordic model of neo-corporatism allowed Denmark, Finland and Sweden to leverage a history of state-industry or industry-labor relations to foster creative investments in R&D or skills development, allowing these small states to punch above their weight in high-technology competition. Markets that evolve outside the purview of

regulators initially operate in a legal vacuum, or in regulatory grey areas. Newman (2008) has detailed the evolution of limited and comprehensive privacy regimes in the US and EU as responses to the increasing prevalence of electronic personal data in industrial societies. He argues that the development of very high regulatory capacity in the EU let them respond with stricter privacy rules than the self-regulation championed by the US. Expertise in transgovernmental networks are a crucial part of the explanation. Both Ornston and Newman are focused on explaining differences in outcomes, and less worried about understanding processes in depth. Understanding, *Verstehen* in the Weberian sense, should be a first step in the study of disruptive innovation given its socially constructed aspects as outlined above.

I suggest that three factors allow innovators to move first: novelty, speed, or obscurity.

Novelty means that the innovation is a product or service that does not fall neatly into any preconceived regulatory category or framework. It will be something new, something that regulators encounter for the first time. Speed means that the innovation creates a market that evolves rapidly, both in terms of reaching a large customer base quickly and in terms of changes in the characteristics of the market (e.g., rapid changes in the number and size of firms or variations in product/service design). Obscurity means that the genesis of an innovation followed a series of developments that were outside the purview of regulators, and that the transactions in the resulting market likewise occur through channels that do not require explicit regulatory involvement or approval. When innovations exhibit all three of these factors, regulators have no choice but to act second.

E-cigarettes are a prime example of an innovation that moved before regulators. Their novelty lies in being a cigarette that does not contain tobacco while being marketed as a healthier alternative. Thus, they do not clearly fit either pharmaceutical or tobacco product regulatory frameworks, as they are previously unseen products that lie somewhere in between (World Health Organization 2010). In terms of obscurity, they were invented in China, and most are still manufactured there (Grana et al. 2014). Their sales initially occurred mostly through internet retailers that sell across national boundaries (Yamin et al. 2010). Regarding speed, internet retail undoubtedly explain part of the rapid uptake and market penetration of e-cigarettes. The growing market for e-cigarettes has attracted a large number of competitors and competing product designs. Some now speak of an “e-vapor market” rather than the market for e-cigarettes due to the growing number of new designs that do not resemble cigarettes (tank-style systems with replaceable cartridges).⁴ Philip Morris, brand owner of Marlboro, recently entered the e-vapor market with a design that heats up actual tobacco leaves instead of a liquid solution to produce a vapor that is more similar to real smoking.⁵ The market is therefore clearly evolving still and will probably do so for a long time to come. Rapid changes are likely in the near future as the big tobacco companies put the weight of their marketing and distribution channels behind their new offerings. Because of the novelty, speed and obscurity of the e-cigarette market, regulators were caught off-guard.

⁴ See <http://blogs.wsj.com/corporate-intelligence/2014/04/14/are-e-cigarettes-losing-ground-in-the-vapor-market/>, accessed October 27, 2014

⁵ See <http://blogs.wsj.com/corporate-intelligence/2014/06/27/introducing-the-new-usb-powered-pack-of-marlboros/>, accessed October 27, 2014

There are other examples of disruptive innovations that move first due to the above characteristics. The market for personal data fits the bill (Newman 2008). Internet giants such as Google, Facebook or Amazon are notorious for their innovative data mining techniques, and they have created a market for trading personal data for the purposes of advertisement or security. This raises the question of whether all disruptive innovations move before regulators? While e-cigarettes and data mining are certainly disruptive innovations, not all disruptive innovations will pressure regulators in the same way. Disruptive innovations can be novel, obscure and fast-moving without requiring or resulting in any actions on the part of the regulators. Bower and Christensen's (1995) classic example of the computer disk drive industry is an example. The speed with which successive generations of disk drive technologies overturned the previous one caused the authors to describe this industry as the fruit flies of the business world, but regulatory involvement was a non-issue. Disk drives are seen to be purely technical improvements. For regulation to become an issue there has to be political salience. In other words, the issue has to be seen as controversial, so that the involvement of politicians and regulators is unavoidable.

In this section I have reflected on the difference between disruptive technologies and disruptive innovations, and the different roles played by innovators (and markets), regulators (and states), and consumers (and the public). Disruptive technologies are repackaged by firms into disruptive innovations that transform markets if they have a compelling value proposition and if market rebels get behind them. The state plays a role in originating disruptive technologies and fostering innovation through policy and investment, but is often placed into a reactionary role from certain types of disruptive innovations. Novelty, speed and obscurity are key factors that allow

innovations to create markets outside the purview of regulators, but regulatory response is only warranted if the innovation has political salience. E-cigarettes are a prime example of an innovation that moved before regulators and now require a regulatory response. These considerations lead into the next section of the paper, where I define the concept of a policy disruption and discuss how regulators can attempt to meet this challenge. The purpose of the section will be to answer the question: What is it that causes the regulatory pressure of some disruptive innovations, and how is this resolved?

Policy disruption

For disruptive innovations to be politically salient, they have to result in contentiousness – that is, they have to provoke argument. For something to provoke political argument, there must be disagreement regarding social processes or outcomes (Rawls 2013). Imagine a specific distribution of harm and benefit in a society before a disruptive innovation (t_0), the occurrence of a disruptive innovation (t_1), and a specific distribution of harm and benefit after the disruptive innovation (t_2). Comparing the distribution at t_0 with the distribution at t_2 allows one to gauge the justifiability of the change. If there is considerably more harm than benefit, there are grounds to resist the change. By looking at how the innovation proceeded during t_1 the permissibility of the innovation can be assessed. For example, if the distribution of benefits is justifiable, but it was made possible by killing people, then there are also grounds to resist the change. It follows then, that politically salient innovations are controversial innovations: those where the permissibility of the innovation and the justifiability of its consequences are called into question.

While this is a useful thought experiment, it is immediately apparent that there is no objective standpoint from which such assessments can be incontrovertibly demonstrated. How the processes and consequences of an innovation are evaluated depends on perspective and interpretation. The *act* of calling the innovation into question is important in itself. There could exist innovations that are neither permissible nor justifiable, but if this is not realized by persons, perceived as such and acted upon, the innovation will remain uncontroversial. Innovators or regulators can also withhold information or frame innovations in a certain way to influence perceptions of permissibility and justifiability. This influences the type of expertise that is brought to bear on the issue and the resulting estimations that policymakers work from, as has been demonstrated in how researchers grossly underestimated the fire damage from atomic bombs, even while making accurate predictions of the nuclear blast, leading to overproduction (Eden 2004).

Controversy and political salience is intersubjectively constructed, but it follows from some underlying material conditions that the innovation causes, namely the distribution of benefit and harm and the way these came about. According to Adler (1997, p.322): “the manner in which the material world shapes and is shaped by human action and interaction depends on dynamic normative and epistemic interpretations of the material world.” Being novel phenomena by definition, any disruptive innovation will initially be open to interpretation by societal groups, who viewing it from their respective positions are likely to arrive at contrasting answers to the following questions: what *is* the innovation, what does it *do*, and what does it *mean*? Any purely instrumental-rational calculation or estimation of an innovation’s utility to a society will never address the question of what that innovation means. The answers to these questions require normative judgments.

It is crucial that the decision not to regulate the disruptive innovation, to leave the topic untouched, be seen as politically charged as well. The realization that the innovation itself benefits or harms certain people through its processes or consequences is what builds regulatory pressure. Benefit or harm should be broadly interpreted: I do not mean to imply solely bodily harm or economic benefits, for example, but also harm to values held by different groups. An innovation that carries the risk of environmental harm is also harming those people who value the environment highly, even without any direct causation that would harm them bodily or economically.

E-cigarettes are controversial and provoke argument. They permit a redistribution of benefit and harm that has been called into question (West & Brown 2014): for instance, there is a potential for harm reduction from smoking, but it could be contingent on supporting the tobacco industry, which is a harmful industry in public health terms. Therefore, in answering the question, “ought we to restrict or ban the sale of e-cigarettes?” there will be strong disagreement. Computer disk drives, on the other hand, have not resulted in a redistribution of harm or benefit that has been called into question. Most agree on the benefits of better disk drives, and the material conditions of the change are not conducive to drumming up a controversy. Therefore, there has been little need for political involvement in this sector. This conception of controversy leaves room for both material conditions and human agency. Opponents of a specific disruptive innovation can seek to restrict it by drumming up controversy and getting political involvement, but this is difficult if the material conditions of the innovation are not easily given to interpretations that make it seem unjustifiable or impermissible. Once an innovation comes to be seen as controversial however, it will be very difficult to defuse the situation, because any attempt at doing so will be viewed as politically motivated and hence controversial in itself.

When regulators are able to move before controversial innovations, they can steer the market and mitigate risks, but controversial innovations that move before regulators put them in a difficult position. There is pressure to act, no consensus, and any decision will be politically charged because it implies a normative judgment as to the justifiability and permissibility of the innovation. It could be argued that this is true of any regulatory decision, to which the answer would be that this is a matter of degree. In regulating controversial innovations, these features are brought starkly into focus.

While controversy is what creates regulatory pressure (and novelty, speed and obscurity allows the innovation to move before the regulators), there are three other aspects of disruptive innovations that make them particularly difficult targets for regulation. The first of these is the highly technical nature of disruptive innovations, as they are often made possible by utilizing new technologies, whose functioning and impact require specialized knowledge to address. This forces regulators to draw on external networks of specialists and professionals with knowledge of the relevant technologies or industries to gain access to the required technical insights (Tushman 1977; Haas 1989; Levi-Faur 2005). Second, disruptive innovations are complex in terms of the high degree of uncertainty as to their use and risks, especially considering that their externalities might affect unexpected sectors of society. This means that regulation is at high risk of being ineffective, inadequate, or simply poorly targeted. Finally, disruptive innovations tend to be transnational, in the sense that their effects are felt across national boundaries. This applies to both potential harmful and beneficial effects. For regulators, this can make it very difficult to act unilaterally, as effective regulation would require the involvement of regulators outside national boundaries.

Having thus considered the characteristics of disruptive innovation as they pertain to regulators, how may we conceive of a regulatory impact of disruptive innovation? Figure 1 below depicts what I define as ‘policy disruption’. It is an ‘ideal type’ – it depicts a theoretical abstraction derived from empirical observation, but fictional in the sense that it does not (and should not) completely and accurately reproduce a real-world phenomenon (Weber 1949).⁶ However, it is a construct or heuristic that we can use to further our understanding of disruptive innovation. The x-axis measures the passing of time (t) while the y-axis measures the rate of change (Δ). The rate of change can be measured both in the market (M) and in the regulatory capacity (R) to oversee that market. From t_0 to t_1 , the market is in a state of equilibrium and is exhibiting a constant rate of change corresponding to the normal evolution of a mature market. The regulatory capacity during this stage is greater than the rate of change in the market, posing no difficulties for regulators to monitor the market and ensure it is well-functioning. This is in other words the status quo of a mature market with settled institutional arrangements.

<<< INSERT FIGURE 1 HERE (LOCATED IN APPENDIX) >>>

At t_1 , the market experiences a disruptive innovation. This greatly increases the rate of change in the market. At t_2 , the rate of change in the market surpasses the capacity of regulators to keep up. This gap increases over time as long as the regulators are unable to adjust regulatory dynamics to the new market realities, creating a swiftly growing regulatory deficit or policy disruption (PD). This definition proposes a further distinction in addition to disruptive technology versus disruptive

⁶ Indeed, ideal types are “meant to be broken” (Seabrooke 2007). They are methodological utopias to be held up and compared to empirical observation in order to highlight variation.

innovation. *Policy disruption is the political fallout of a disruptive innovation.* It manifests itself in a change in the material conditions of a market (either an existing one or a new one), which leads to an invalidation of existing regulatory expectations, norms, ideas and frameworks, and pressure to accommodate and eliminate this invalidation. Not all disruptive innovations lead to policy disruptions. First, there is the requirement that the innovator moves before the regulator. This happens when the innovation lives up to the criteria of speed, novelty and obscurity as defined above. Second, the innovation has to be controversial in order to enter public and political debate. If these are the criteria that lead to the creation of a policy disruption, then the remaining characteristics of disruptive innovations sustain the policy disruption, or make it difficult for regulators to eliminate the regulatory deficit. These were defined above as being technical, complex and transnational. Finally, controversy plays a part in sustaining the policy disruption as well, due to the difficulty of politically resolving conflicting value judgments.

How is the policy disruption adapted to? Figure 1 implies that to eliminate the deficit, either regulation must be made faster or the market must be made slower. The market can be made slower either by industry putting voluntary restrictions in place (motivated by a wish to mitigate the risks of expanding too quickly into unknown territory), or by regulators putting bans, restrictions, requirements or mandatory standards into effect. Examples of regulation being made faster include industry self-regulation or voluntary standards (Ponte & Gibbon 2011), or regulators delegating to specialized agencies (Levi-Faur 2005), networks (Wright 1988), or private authority (Braithwaite & Drahos 2000), or engaging in experimentalist governance (Sabel & Zeitlin 2008). It is an open and interesting question for research as to which mix of strategies and roles are pursued in different cases.

This typology of strategies to adapt to policy disruption is reminiscent of Bütthe & Mattli's (2011) typology of global regulation. They divide global regulation into public and private institutional settings, and market-based versus non-market based selection mechanisms. This leaves us with rule making in a focal international organization, rule-making by transnational standard-setting bodies, and competing standards developed in either public or private settings. It is a task for future research to combine Bütthe & Mattli's typology with the one developed here by adding in considerations of regulatory and market 'pace' and responses that do not require regulation or rule-making per se, such as voluntary restrictions on market activity. Table 1 below provides an overview of the theoretical argument.

<<< INSERT TABLE 1 HERE (LOCATED IN APPENDIX) >>>

How well do e-cigarettes fit the schemata of a policy disruption? Their speed, novelty and obscurity has been demonstrated in an earlier section, allowing this market to move before regulators. Controversy is certainly a factor too, stemming from the disagreement as to whether they are pharmaceutical quitting devices or tobacco products, two different conceptions with differing market, cultural and regulatory consequences. There is also controversy regarding their safety and their effect on smoking cessation and public health, which leads into the characteristic of complexity. There are fundamental unknowns about e-cigarettes that were described in the introduction, and that cannot be resolved in the short term. In terms of technicality, addressing some of these unknowns and making educated guesses is dependent on specialized expertise residing for example in the medical or public health profession. The transnational effect of e-cigarettes lies in their transmission over internet sales

channels and their adoption by multinational tobacco corporations, both of which have allowed them to spread rapidly and be advertised widely, through social media for example (Yamin et al. 2010).

Evidence of the policy disruption exists in the form of statements from media observers regarding the “regulatory Wild West”⁷ and direct statements from regulators such as the European Commission concerning the revision of the Tobacco Products Directive: “New products such as electronic cigarettes have entered the market and some of the current provisions of the Directive have become outdated. The legislative proposal aims at making tobacco products and tobacco consumption less attractive, and thus to discourage young people from starting to smoke” (European Commission 2012a). The pressure to act thus comes from the perceived threat that e-cigarettes are especially enticing young people to take up smoking, further backed up by the statement: “Novel products such as electronic cigarettes have entered the market and recent marketing strategies involve the use of attractive packaging and flavours” (European Commission 2012b). Finally, the press release gives an indication of the envisioned time frame for these changes: “It is expected to be adopted in 2014. It would come into effect from 2015-2016” (European Commission 2012b). A threat thus identified in 2012 still allows at least 3-4 years before the regulatory changes come into effect on the EU level. As mentioned, from 2012 to 2014 the number of vapers in the United Kingdom grew from 700,000 to 2.1 million, meaning that the e-cigarette market is expected to expand rapidly in the same period.

National legislation may come into effect sooner than this, but it will not necessarily guard against the

⁷ See e.g. <http://www.npr.org/2013/10/21/239269426/e-cigarettes-a-nearly-2bn-industry-a-regulatory-wild-west>, accessed October 24, 2014

transnational effects of e-cigarettes in the same way that EU regulation would. Everything suggests that policy disruption is a very real phenomenon in the case of e-cigarettes.

What strategies are being pursued to adapt to the policy disruption? The regulatory changes aimed at slowing down the market have been mentioned already, but their time frame allows the disruption to persist for 3-4 years. There is currently no indication that any formal delegation of regulation in this sector is being transferred to specialized agencies or private bodies, but the e-cigarette industry in the EU has established the Electronic Cigarette Industry Trade Association (ECITA), which has proposed an industry standard.⁸ The standard is motivated by the desire to steer regulation in a specific direction: “In light of the current regulatory situation – both nationally and internationally – the UK Electronic Cigarette Industry has formed a united and cohesive body to ensure the correct regulatory framework is applied to these products now and for the future.”⁹ The added benefit of such a standard from an industry perspective is to signal “quality, safety and superiority of ... products and services” as well as “credibility” and “ethical business practices.”¹⁰ Adapting to policy disruption is in the interest of both regulators and innovators. When policy disruption persists, uncertainty prevails and the rules of engagement on the market are unclear. This might ultimately hurt businesses seeking public legitimation to secure the parameters of their growth and manage expectations.

⁸ See <http://www.ecita.org.uk/>, accessed October 31, 2014

⁹ Ibid.

¹⁰ Ibid.

Conclusion

This paper has used the case of e-cigarettes to introduce the concept of policy disruption. Policy disruptions are the political fallout of disruptive innovations. Disruptive innovations that are controversial and whose markets develop outside the purview of regulators cause policy disruption. Throughout the text, I have returned to the example of e-cigarettes to provide empirical grounding to the theoretical arguments made. Policy disruption is important to study in its own right. In the literature, there is a dearth of theoretical and empirical work on the regulation of fast-moving, controversial markets, and especially on how the characteristics of such markets change the conditions of policymaking. The characteristics of policy disruption make the pre-social determination of policy actors highly problematic. Most theories of the policy process proceed from a deductive position by ascribing certain identities or interests to actors based on material conditions, beliefs, organizational culture, or institutional affiliation (Sabatier & Weible 2014). Due to the complex, uncertain, highly technical and rapidly changing characteristics of disruptive innovations, actors have no stable basis of material conditions on which to form interests (Woll 2008). Focusing on organizational culture and identity overlooks the prevalence of 'revolving doors' (Seabrooke & Tsingou 2009) and the intra- and trans-institutional maneuvering of professionals in policy problems that require a broad variety of expertise to deal with (Seabrooke 2014; Seabrooke & Tsingou 2014). In these situations, it is a more prudent analytical position to let interests and identities emerge out of social interaction and not assume that they determine it.

The 'practice turn' in International Relations (IR), drawing heavily on Bourdieu and Geertz, argues that formal and informal processes of social interaction (practices or patterns of behavior) should be the default analytical unit (Pouliot 2008; Adler & Pouliot 2011; Adler-Nissen & Pouliot 2014). The advantage of the practice turn is its analytical and empirical granularity: being able to see big answers in small questions, moving from the specific to the general and not vice versa, and giving importance to everyday actions and interactions. This brings the analysis closer to reality as experienced by the practitioners. Through induction and the thick description of social context, it is possible to go from the micro to the macro and back. Bourdieu beckons us to pay "attention to the most trivial data, which other [approaches] feel entitled to ignore, in the name of a right to abstraction that is seen as constitutive of the scientific approach, [in order to construct] models that are empirically validated and capable of being formalized" (Bourdieu 2008, p.5).

In situations of complexity such as policy disruption, focusing on practice becomes even more important. When standard procedures or models are invalidated, expertise comes to the foreground. Expertise has been theorized as virtuoso social acting (Bourdieu 1977) and context-dependent intuitive acting as opposed to context-independent analytical thinking (Dreyfus & Dreyfus 1986). Expert actors are seen as people with a feel for the game, who often act on instinct or gut feeling. Policy disruptions require heavy involvement of such expert actors to defuse extraordinarily difficult situations. Expert actors come together in social interactions to navigate the issue and propose solutions. Theories that start from a position of general, context-independent models will have a difficult time dealing with these situations and truly understanding how people act (Flyvbjerg 2001). While the advantage of such theories are simplicity and broad application, their disadvantage lies in a thin description of the

case-specific mechanisms. It is in the thick description of case specificities that much valuable social research has been made, and it thus seems that there is a need for a practice-oriented theory of the policy process to complement the many other approaches. An initial foray into this territory would do well to take heed of the lessons drawn from the practice turn in IR, as well as the emerging transnational (political) sociology of the professions (Faulconbridge & Muzio 2012; Seabrooke 2014). I suggest that to gain traction on the technological traits and uncertainties driving policy disruption much could be learned from science and technology studies, and specifically the notions of ‘trading zones’ (Galison 1997) and ‘technological zones’ (Barry 2006), although this task has yet to be taken up.

It may seem that policy disruption bears a lot of resemblance to theories of crises, shocks, punctuated equilibrium, and so forth. It is important to specify why policy disruption is different and why it is important to study. Policy disruption differs from theories that deal with shocks or crises in especially two important ways. First, policy disruptions obey some of the same rules as shocks and crises do, but this is overlooked in the case of policy disruptions. In one sense, they are crises that are not recognized as crises. In spite of the talk of a “regulatory Wild West”, the regulation of e-cigarettes is not labelled a crisis and does not lead to periods of extraordinary measures and politics, but there are still similarities to ‘real’ crises such as the financial crisis. In both cases, there is a poorly understood market whose pace of change has sorely outstripped the capacity of regulators to keep up with and adapt to that change. While the effects of the financial crisis were much more widely felt than any effect of e-cigarettes will be, both cases are equally interesting if we are interested in the processes of regulation, governance and market development. This raises the question: “Why not just study crises then?” Policy disruptions do not result in a suspension of normal politics as crises do

(Balcerowicz 1994). It is interesting to study how regulators respond to crisis-like situations that are not recognized as crises through normal policy processes. Furthermore, crises and shocks tend to be seen as one-off, exogenous events that upset a system, such as natural disasters. Policy disruptions leaves more room for endogenous processes and for the continuing development and increasingly rapid pace of change following the initial onset of disruption. Finally, policy disruptions broaden the empirical material considerably to allow scholars to consider these dynamics in a bigger population of cases. Other examples include the regulation of hydraulic fracturing (fracking) for shale gas, digital piracy of audiovisual entertainment, the market for personal data, and illegal marketplaces on the Darknet (such as Silk Road).

Another reason policy disruption is important is that it can be seen as the micro-scale motor driving the macro-scale co-constitution of states and markets over time (Polanyi 1944; Blyth 2002). Technological change tends to be theorized on the macro level as a necessary engine of creative destruction that keeps reproducing the conditions for capitalism (Schumpeter 1942), resulting in economic growth (Lipsey et al. 2005) and societal changes in skills and work patterns (Brynjolfsson & McAfee 2014; David et al. 2003; Berman et al. 1998). Little attention has been given to the micro-scale processes that make these macro-scale developments possible. To study policy disruption is to study the discrete instances of confluence and co-constitution of technological change, governance and markets that drive macro-scale societal development.

Tables and Figures

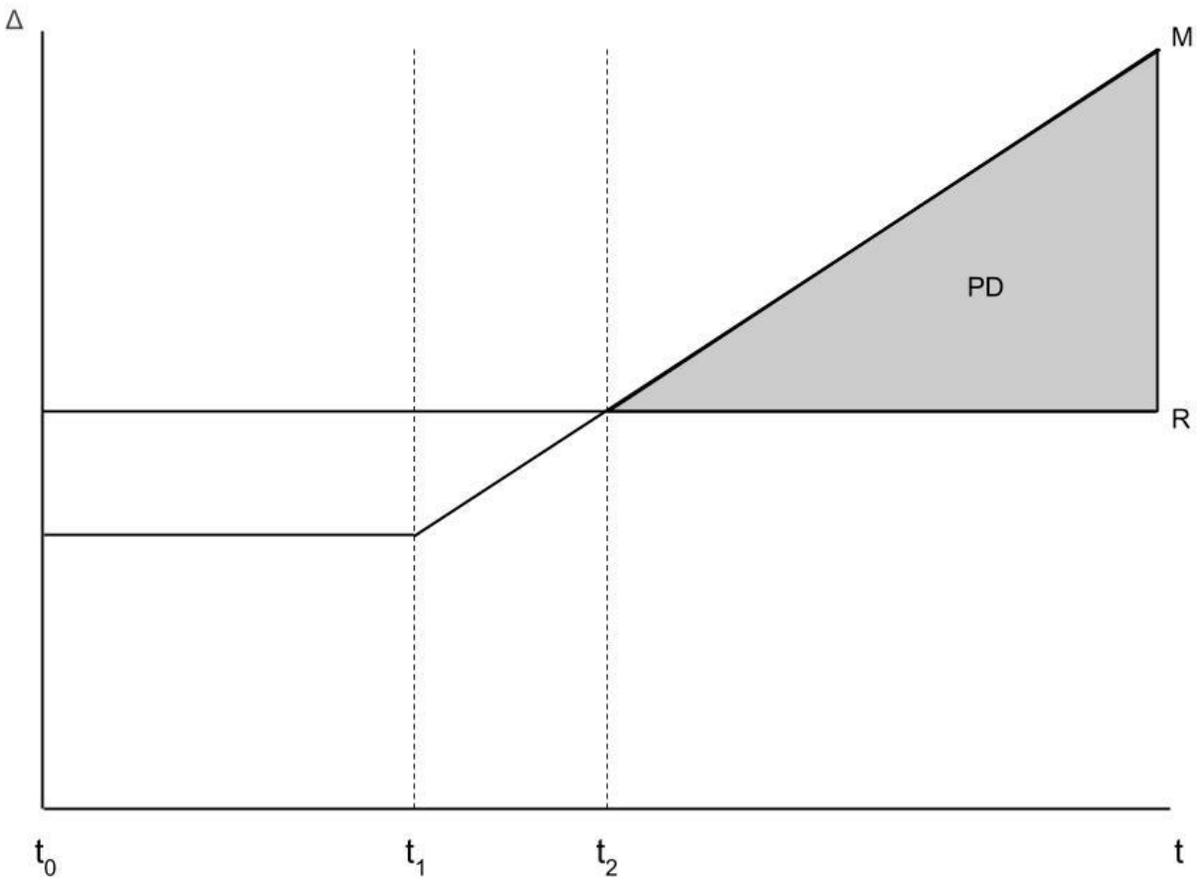
Figure 1. Policy disruption

Table 1. Creating, sustaining and adapting to a policy disruption

Characteristics of disruptive innovation		What does this mean for the innovator?	What does this mean for regulators?
Creating a policy disruption	Fast-moving	Rapid market growth and change	Regulation becomes outdated, time pressure
	Novel	Creates new markets and practices	Innovation does not fit neatly into existing regulatory frameworks
	Obscure	Hidden or unobserved genesis and initial transactions of the innovation	Regulators unaware of innovation’s origin and development
Sustaining a policy disruption	Technical	Require professionals and expertise	Importance of specialists (instead of generalists) and external networks
	Complex	Uncertainty and unexpected outcomes	Regulation may be inadequate or ineffective, not correctly targeted
	Transnational	Effects ignore state boundaries	Difficult to address unilaterally
Creating and sustaining policy disruption	Controversial	Creates benefit or harm to certain groups through its process or consequences, and the meaning of the innovation is open to interpretation	Builds regulatory pressure to act, lack of consensus, invites conflicting normative judgments
Adapting to policy disruption	Making the innovation slower	Voluntary restrictions to lower market risk	Bans, restrictions, requirements, mandatory standards
	Making the regulation faster	Self-regulation, voluntary industry standards	Delegating to specialized agencies and networks, private authority, experimentalist governance

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