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When risks cannot be seen: Regulating uncertainty in emerging technologies

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ABSTRACT

Commercializing an emerging technology that employs an immature production process can be challenging, particularly when there are many different sources of uncertainty. In industries with stringent safety requirements, regulatory interventions that ensure safety while maintaining incentives for innovation can be particularly elusive. We use the extreme case of metal additive manufacturing (an emerging technology with many sources of process uncertainty) in commercial aviation (an industry where lapses in safety can have catastrophic consequences) to unpack how the characteristics of a technology may influence the options for regulatory intervention. Based on our findings, we propose an adaptive regulatory framework in which standards are periodically revised and in which different groups of companies are regulated differently as a function of their technological capabilities. We conclude by proposing a generalizable framework for regulating emerging process-based technologies in safety-critical industries in which the optimal regulatory configuration depends on the industry structure (number of firms), the performance and safety requirements, and the sources of technological uncertainty.

1. Introduction

New manufacturing techniques bring challenges associated with their technological uncertainty, which requires the development of process understanding and control procedures to transition "from art to science" (Bohn, 2005). This can be critical to broader commercial viability and adoption. Examples in the literature include biotechnology (Pisano, 1991), chemicals and pharmaceuticals (Pisano, 1997; Straathof et al., 2002), semiconductors (Bassett, 2002; Bohn, 1995; Holbrook et al., 2000; Lécuyer, 2006), optoelectronics (Fuchs and Kirchain, 2010) or aircraft manufacturing (Mowery and Rosenberg, 1981).

Traditionally, approaches to regulate risk have been divided into technology-based, performance-based and management-based regulation (Coglianese et al., 2003). Each approach incentivizes a different level of innovation at firms, and tackles technological uncertainty in a different way. Technology-based regulation decreases uncertainty by mandating the use of a certain technology, but may limit innovation and the adoption of new technologies and processes (Dudek et al., 1992; Jaffe and Stavins, 1995; La Pierre, 1976; Stewart, 1991). Performance-based regulation allows firms greater opportunities for innovation, but it does not work well when it is difficult to demonstrate that the desired performance has been achieved (Coglianese et al., 2003; Downer, 2007; Notarianni, 2000). Management-based regulation aims to shift the decision to the actor with the most information (Coglianese and Lazer, 2003; Downer, 2010). Such actors have a better understanding of the risks and benefits of the technology. However, implementing management-based regulation is more difficult than the other approaches, and history shows that engineers may underestimate risks (Petroski, 1992). Independent of the approach taken to regulating them, the emergence of new and uncertain technologies such as biotechnology, nanotechnology or climate change mitigating technologies, has led to an increasing demand for adaptive regulation that is periodically revised to ensure that it updates its content to incorporate the latest available knowledge (McCray et al., 2010; Oye, 2012; Wilson et al., 2008).

We use metal additive manufacturing (MAM), an example of an emerging technology with many sources of uncertainty; and civil aviation, an industry with stringent safety standards but for which MAM promises many performance benefits, to analyze regulatory needs as a function of technological uncertainty. We triangulate archival data, 37 semi-structured interviews, and 80 hours of participant observations

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(Jick, 1979), including insights from an invitational workshop we ran in Washington, D.C. with 25 leaders from government, industry and academia. We use grounded theory-building methods (Eisenhardt, 1989; Glaser and Strauss, 1967) to reveal the process by which MAM and other technologies are regulated in commercial aviation, and the complex intertwine between innovation and uncertainty.

We find that there are still many sources of uncertainty surrounding MAM in terms of material supply, equipment configuration, process control, and post-processing procedures. In an industry such as aviation with a marked "learning by using" component, some of this uncertainty may only be revealed with flight experience. There are also important differences across the supply chain in terms of knowledge, financial resources, goals, and regulatory oversight which may result in additional sources of risk. Current certification procedures are not well-suited to dealing with this uncertainty and to the variation in competence across the industry. At the same time, currently proposed mechanisms to regulate MAM products may affect the long-term competitiveness of the technology. To balance the need for safety and innovation, new adaptive regulation mechanisms are needed for when the technology is still immature.

This paper contributes to the literature by clarifying how, for a specific emerging technology, different sources of uncertainty may change the optimal regulatory design. In addition, we show how the differences in their underlying motivations and technology capabilities across supply chains may create the need for additional collective action to ensure an adequate level of safety. We leverage the extreme case of MAM in civil aviation. Iterating between our findings and existing theory on technological uncertainty and the regulation of technological risks, we propose a new typology for considering the regulatory tradeoffs between safety and the sources of technological uncertainty across different technologies and industries.

2. Literature review

2.1. Technological uncertainty in immature technologies

Development of an emerging technology is marked by a progressive decrease in the levels of technological uncertainty and variability in the production outputs, a transition which Vincenti (1990) coined as "from infancy to maturity" and Bohn (2005) as "from art to science".[1] Examples of industries where these uncertain maturation processes have been paradigmatic include biotechnology (Pisano, 1991), chemicals and pharmaceuticals (Pisano, 1997; Straathof et al., 2002), semiconductors (Bassett, 2002; Bohn, 1995; Holbrook et al., 2000; Lécuyer, 2006), optoelectronics (Fuchs and Kirchain, 2010) and aircraft manufacturing (Mowery and Rosenberg, 1981). These examples are notably dominated by chemical- and advanced-material-based products, as well as in the case of aircraft manufacturing, complex, multi-part interdependent systems.

In the early years of an emerging technology, scientists often have difficulty explaining why a particular piece of equipment or process does or does not work as expected. Production yields are low due to the inability of establishing robust relationships between production inputs and outputs. There is also a lack of adequate process control (Bohn, 1995); Learning which production step is the cause of such variability can be slow (Balconi, 2002). For instance, Collins (1974) explains how in the early stages of the development of laser technology, a group of scientists made what appeared to be an exact replica of a working laser, yet failed to make it work and finally gave up.

As experts start accumulating knowledge, they forge intuitive models about the underlying mechanisms that govern the processes and begin to implement some amount of process control. At this stage, similar to traditional crafts in which apprentices learn from their masters (Bohn, 2005), knowledge is mainly tacit (Polanyi, 1958) and thus results cannot easily be replicated even within the same firm, and often less in an outside firm (Teece et al., 1997). Yields improve as knowledge is created, but when the science of production at large volumes is fundamentally different than that at small volumes, it may still not be good enough for commercialization (Pisano, 1997). The same may be true if the emerging technology is unable to be profitable against the incumbent technology given consumer preferences in present-day markets (Fuchs and Kirchain, 2010). Even when knowledge improves through experience to the point that it can be codified, as for example in the form of checklists and standard operating procedures, it may take a long time for the basic underlying science to be understood well enough for that knowledge to be applied in contexts that are substantially different from those in which the experience was gained (de Solla Price, 1984; Semmelweis and Murphy, 1981). Often only after the development of theories and mathematical models to explain the behavior of the technology, is knowledge generalized such that results can be systematically replicated, arriving at what Bohn (2005) calls "science."

During the maturation period, firms may acquire knowledge in a different manner which allows them to control the sources of uncertainty and reduce manufacturing costs. For the design of complex parts, Fleck (1994) describes a process he calls 'learning by trying', in which engineers perform small changes to the constituents until a final working configuration is achieved. Similarly, in the context of manufacturing, Arrow (1962) describes a process he calls "learning by doing" in which through repeated experience producers become familiar with the problems that arise during the manufacturing process and are able to implement slight modifications. In the context of aircraft manufacturing, Wright (1936) proposed one of the first models of a "learning curve," an empirical relationship between the number of units produced and a decline in unit cost. Nevertheless, some aspects of a technology may only be revealed in the use phase of the final product, due to the inability to cost-effectively simulate those conditions (or the length of exposure thereto) in a test environment. This 'learning by using', had a central role in reducing uncertainty about the performance of new aircraft in the early 20th century (Mowery and Rosenberg, 1981). Learning by using has proved particularly important in reducing the uncertainty surrounding new materials like advanced composites in aircraft (RAND, 1992). Learning by using sometimes reveals unexpected behaviors like the propagation of fatigue cracks that occurred along the square-shaped advanced windows of the De Havilland Comet aircraft, and which led to a series of catastrophic accidents (Withey, 1997). Downer (2011a) coined the term "epistemic accidents," defining them as 'accidents that occur because a scientific or technological assumption proves to be erroneous, even though there were reasonable and logical reasons to hold that assumption before (although not after) the event.' Epistemic accidents are unpredictable and more likely to occur when working with emerging technologies (Downer, 2011a).

The speed at which technology is able to mature from art to science is affected by both its particular characteristics and by contextual factors. Technology characteristics include the number of input variables and their interaction (Macher, 2006), the total number of parts (Singh, 1997), the total amount of information (von Hippel, 1994), the existence of appropriate measurement techniques (Brown and Duguid, 2001), and the ability to test during intermediate production stages (Lécuyer, 2006). Furthermore, innovation in the form of new procedures (Fleck, 1994; Pisano, 1997), new process control mechanisms (Hatch and Mowery, 1998) and complementary technologies such as specific testing equipment (Lécuyer, 2006) are normally needed to reduce variability in manufacturing. Examples of contextual factors affecting technology's evolution are technological diversity (David and

[1] The transition described by Bohn (2005) is closely related to the classic literature of product life-cycle, including the dynamics of product and process innovation (Gort and Klepper, 1982; Utterback and Abernathy, 1975; Vernon, 1966). These papers put more focus on the implications of the dynamics of technological change for industry structure and entry and exist of firms, as well as the destruction of established ones. As we are more focused on the evolution of technological uncertainty in manufacturing, we focus our discussion more around the literature by Bohn (2005) and Vincenti (1990).