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Converting clinical risks into economic value: The role of expectations and institutions in health technology development

P. Lehoux^{a,*}, F.A. Miller^b, G. Daudelin^c

^a Department of Health Management, Evaluation and Policy, University of Montreal, Institute of Public Health Research of University of Montreal (IRSPUM), P.O. Box 6128, Branch Centre-ville, Montreal, Quebec H3C 3J7, Canada

^b Institute of Health Policy, Management and Evaluation, University of Toronto, Canada

^c IRSPUM, University of Montreal, Canada

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ABSTRACT

The ability to handle clinical and business risks is critical to an academic spin-off that seeks to develop a new medical technology. The milestones it has to meet to materialize its innovation are objects of speculation for those who finance its operations, and also for stakeholders who comment publicly on its progress. Such future-oriented expectations are not, however, mere hype since they operate within a set of practices that are highly institutionalized. Building on insights from sociology of expectations and institutions, this paper elicits how specific institutional requirements provide potency to the expectations that pave the health technology development pathway. Nested within five years of qualitative fieldwork, our study relies on a media coverage analysis to examine, over a decade, technology development in five Canadian spin-offs. Our findings illustrate a three-step process that involves: 1) measuring clinical risks that are convertible into business opportunities; 2) structuring technological entrepreneurship for growth; and 3) mitigating commercial risks to protect the spin-offs' economic value. Over time, expectations and institutions redefine where risks and opportunities lie, converting clinical risks into economic value. While the spin-offs support speculative economic value extraction, the technologies they materialize may fall short of fulfilling their clinical promises.

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1. “What if” expectations in innovation policy

Technological innovation in a knowledge-based economy is “an intensely future-oriented business with an emphasis on the creation of new opportunities and capabilities” (Borup et al., 2006: 285). As a result, future-oriented expectations pervade innovation policy. For instance, in their report to the Canadian Government, the members of the Independent Panel on Federal Support to Research and Development took care to provide an explanation for their cover page, which featured a geographical representation of the country lifted up by a glowing light bulb. The explanation goes as follows:

While the great American inventor Thomas Edison is given credit for “inventing” the light bulb, the story is really one of incremental innovation. In 1810, British chemist Humphry Davy invented the “electric arc,” a precursor to the light bulb. A series of innovations followed and, by the 1860s, the race was on to develop a commercially viable light bulb. Joining this race were two Canadians, Henry Woodward, a medical student in Toronto, and Mathew Evans, a hotel keeper. In 1874, they patented a nitrogen-filled light bulb that

lasted longer than others of the era. But they could not get financing for their work, and in 1878 were eclipsed by British inventor Joseph Swan and then in 1879 by Thomas Edison. Realizing the commercial viability of the light bulb, Edison was successful in obtaining major financial backers. He used these funds to continue his experiments, but also to buy out many patents, including those of Swan and of Woodward and Evans.

As we reflected on our consultations held across Canada, during which we heard first-hand of the struggles and successes of Canadian entrepreneurs, we wondered: What if Woodward and Evans had been able to interest investors? What if they had been able to obtain financing to carry on their work and beat out Swan and Edison to be the first to commercialize the light bulb? (Jenkins, 2011).

This story resonates well with the idea of a knowledge-based economy in which commercial entities “seek capital, in the form of speculative investment, to transform [research-based] discoveries into commercial products and services” (Morrison and Cornips, 2011: 264). The story also illustrates two key observations from the sociology of expectations (Borup et al., 2006; Brown and Kraft, 2006; Brown and

* Corresponding author.

E-mail address: pascale.lehoux@umontreal.ca (P. Lehoux).

Michael, 2003). First, by foregrounding a likely rivalry between inventors located in different countries, the story casts Canada as racing against the United States and Britain. Albeit it does so implicitly, the story designates winners and losers, thereby setting the stage for a particular past political economy to be understood (Brown, 2003). Second, the “what if” questions encourage readers to envisage a more desirable future. The speculations about Canadian inventors’ ability to attract investments and surpass their British and American counterparts capture the main thrust of the Report, which posits securing access to capital as the key turning point in the light bulb development story. Contemplating such “what if” questions opens up a straightforward path of action to the Government of Canada, eager to see a wealthier future unfold.

Future-oriented expectations highlight the mustering power of imagination in the innovation landscape. Yet, in the capital-intensive and highly institutionalized world of health technology development, which involves clinical trials, regulatory approvals and eventually stock exchange transactions, one should ponder not only how expectations function in scientific, policy and media discourse (Nerlich and Halliday, 2007), but also how they operate in practice (Pollock and Williams, 2010). For how long does a promising new technology remain promising? What counts as concrete progress? And what happens if expectations are not met?

The goal of this paper is to empirically elicit how specific institutional requirements provide potency to expectations. To do so, we rely on a qualitative media coverage analysis that was nested within five years of fieldwork in which we examined how, over an eleven-year period, five Canadian spin-offs developed and commercialized new health technologies. As a young company emerging from a public research setting, an academic spin-off faces soaring expectations that have to do with its future (Vohora et al., 2004). Its ability to handle clinical and business risks is critical. The milestones it has to meet to materialize a new technology are objects of speculation not only for those who finance its operations, but also for those who comment publicly on its clinical, commercial and financial progress (Morrison and Cornips, 2011). Over time though, concrete achievements and shortcomings become matters of scrutiny and the gap between expectations and the material world becomes more problematic.

By explicitly considering how institutions both constrain and enable certain forms of action in technology development, this paper endeavours to fill a key research gap: the role of institutions is largely missing from sociological analyses of expectations in innovation development (see, for instance, the special 2006 issue of *Technology Analysis & Strategic Management*). Adopting a sociological perspective, an important contribution of this paper is to provide empirical observations that clarify the process by which future-oriented expectations support speculative economic value extraction even if the technologies being materialized fall short of fulfilling their clinical promises. Process-oriented research like that reported in this paper involves constructing an in-depth narrative of actions that unfold over time in order to generate “concepts, understanding, and theory closely linked to data” (Ferlie et al., 2005: 119). Such research can help enrich theoretical models and revisit the empirical basis upon which policy frameworks rely.

This paper is comprised of four sections. Firstly, we define what expectations are from a sociological perspective and how they provide direction to action within institutionalized practices. We then describe our qualitative data set, emphasizing how we analyzed the media coverage ($n = 814$) of five spin-offs located in Quebec (the second largest health R&D region in Canada) between 1998 and 2009. Thirdly, we empirically illustrate a three-step process that shapes the technology development pathway and involves: 1) measuring clinical risks that are convertible into business opportunities; 2) structuring technological entrepreneurship for growth; and 3) mitigating commercial risks to protect the spin-offs’ economic value. Fourthly, we summarize why research on future-oriented expectations proves insightful when institutional requirements are factored in the analysis and discuss the policy implications of our findings.

1.1. What expectations are and how they provide direction to action

In their simplest form, expectations have to do with imaginings, visions and other kinds of future-oriented abstractions (Berkhout, 2006; Brown and Kraft, 2006; Brown and Michael, 2003). In the case of health technology-based spin-offs, this future may easily span a 10-year period. The term future-oriented expectation thus underscores the long temporal frame within which innovation stakeholders reason and operate. Nerlich and Halliday (2007) suggest that one may distinguish expectations that are understood as *negative* and need to be prevented from occurring (risks, threats, damages, etc.), from expectations that are *positive* and have to “come into being” (scientific breakthroughs, leaps forward, etc.). Notwithstanding the fact that safety issues are rarely if ever settled once and for all (Faulkner, 2008; Jasanoff, 2005), health innovations generally fall into the latter category; the most pervasive wish is to make them come into being. Actors who foster health innovation development usually call upon two categories of positive expectations: social and economic. Morrison and Cornips refer to a “double promise” where the “value of intangible scientific knowledge in the present is closely intertwined with both the projected social benefits arising from new technologies and the concomitant promise of future economic growth” (2011: 264).

Establishing a set of shared expectations is particularly important in commercially oriented R&D. The necessity to bridge different worlds and coordinate actions across venture capital, business and scientific communities is indeed salient (Borup et al., 2006). Innovation developers generate and build on hopeful narratives through which the complex potentials of R&D activities can be translated into promising stories of opportunities for investors and other stakeholders (Fortun, 2001; Petkova et al., 2013; Pollock and Williams, 2010).

Future-oriented expectations may be framed more or less persuasively in order to increase actors’ ability to secure financial resources (6 Perri, 2005), but are always narratives of a particular kind. Expectations have a “pragmatic force” in that they “orientate” groups and individuals to “particular possibilities for action” (Nerlich and Halliday, 2007: 50). Early warnings like early promises are forged by actors to shape visions of the future, but with the intent to affect social and political actions in the present (Berkhout, 2006; Horst, 2007; Rosengarten and Michael, 2009). What provides direction to actors involved in the technology development pathway is the “hoped for end point”: the launch of a successful, revenue-generating technology (Morrison and Cornips, 2011: 271).

Future-oriented claims are located within a broad temporal frame, which may remain implicit but which has to resonate with those one wishes to take action. Morrison and Cornips (2011) call this frame a metanarrative since it tacitly organizes a credible “actionable” path from the present to the expected future. One particularly effective metanarrative in R&D activities is that of a linear, stepwise scientific model:

If extrapolations create a link between the present and future, the already established, recognizable metanarrative of *how* scientific progress is understood to occur serves as an implicit explanation of how the transition will be made from one state to the other (Morrison and Cornips, 2011: 271).

While remaining in the background, the metanarrative articulates a common path—made of a series of successive milestones—for actors to relate to and coordinate their actions around (Pollock and Williams, 2010).

1.2. Locating expectations within institutionalized practices

When expectations around agreed upon milestones capture the interest of necessary allies and help build “mutually binding obligations and agendas” (Borup et al., 2006: 285), sociologists of expectations

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