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**FORESIGHTING FUTURES:  
LAW, NEW TECHNOLOGIES AND THE CHALLENGES OF REGULATING  
FOR UNCERTAINTY**

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**INTRODUCTION<sup>†</sup>**

It is perhaps trite but worth repeating that existing social and legal systems aimed at promoting human wellbeing and prosperity face significant and multi-faceted challenges. Some come from the natural world and some from humankind itself. Of the latter, some come from the way we behave and treat each other, some from the way we interact with and wish to shape our environment, and, most challenging of all, some come from the way we envision and seek to shape our future. Many of these implicate the law. Indeed, never have we demanded so much from our legal and regulatory frameworks and those who operate them, and never have they faced so many pressures and variables. The following captures the character of the times:

Uncertainty ... is the only certainty there is, and knowing how to live  
with insecurity is the only security.<sup>1</sup>

Unsurprisingly, this uncertainty is contributed to – if not driven by – technology. The following poem, offered at the US Library of Congress in 1979, is a worthy expression of the technological contribution to uncertainty:

Technology,  
I used to hope  
For a break-through;  
Now I wonder  
What into?<sup>2</sup>

The technological ‘revolutions’, so often spoken of, compound this uncertainty. For example, new and emerging technologies in the nano, bio, and informational fields

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<sup>1</sup> J. Paulos, *A Mathematician Plays the Stock Market* (NY: Basic Books, 2003), at v.

<sup>2</sup> W. Berry, Address at the US Library of Congress, 1979, as quoted in D. Bazelon, “Science and Uncertainty: A Jurist’s View” (1981) 5 *Harv Enviro LR* 209-215, at 209.

are converging toward a ‘New Renaissance’,<sup>3</sup> or a ‘Fourth Wave’,<sup>4</sup> which is often claimed to be destabilising of many social and legal norms and frameworks.<sup>5</sup> The resultant uncertainty is further radicalised by the uncertainty created around our ‘symbolic order’, viz, the fundamental distinctions and categories upon which we rely for drawing boundaries and understanding reality (eg: healthy and sick, life and death, man and woman, human and thing, etc.).<sup>6</sup> From a social and regulatory perspective, the following has been argued:

New technologies evoke diverse responses. They can seem promising or threatening, or both. To some degree, what we think of them seems to depend on whether they are just around the corner, a distant fantasy or already part of everyday life. What we think of them also depends on how confident we feel about our ability to regulate them and, indeed, on how we react to the prospect of being regulated by them. One thing, however, is clear: negotiating the mix of hope, hype, fear and quotidian use that surrounds new technologies is not going to be easy – either for individuals or groups, or indeed for regulators.<sup>7</sup>

As this quote suggests, we, as a society, have not always been prepared, and are not adequately equipped, to confront concerns and possibilities around technologies in an early, explicit, or effective manner. Indeed, some of the most important and ubiquitous technological innovations of the modern era were ‘rolled out’ with very little consideration on the part of developers and contemporary commentators of the profound social and legal impacts they might have. For example, few recognised the extensive social and commercial influencing potential of faxes or the internet until they had already been taken up,<sup>8</sup> nor had they in any way settled the legal mischief that they might instigate (which mischiefs are, in fact, still evolving).<sup>9</sup>

This paper engages with this technology-driven uncertainty, querying how we might better regulate in the emerging socio-technological setting, which setting is characterised by promise and consternation, fluidity and pace, fragmentation and complexity. In particular, it considers the concept and role of ‘foresighting’. After very briefly examining the evolution of foresighting generally, the paper explores the possibilities for foresighting in the legal setting, arguing that ‘legal foresighting’ is

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<sup>3</sup> So claimed by M. Roco & W. Bainbridge, “Converging Technologies for Improving Human Performance: Integrating from the Nanoscale” (2002) 4 J Nanopart Res 281-295.

<sup>4</sup> Each wave represents a paradigm-shifting technological change; the first was the agricultural revolution, the second the industrial revolution, and the third the information revolution: A. Toffler, *The Third Wave* (NY: Bantam Books, 1980).

<sup>5</sup> See T. Adams, “Radical Destabilising Effects of New Technologies”, Autumn 1999, *Parameters*, 99-111, and Brocher Foundation, “Hastings Centre Summer Academy – Human Enhancement: Medical, Ethical and Legal Implications”, 4-8 July 2011, Geneva.

<sup>6</sup> A concept coined by M. Douglas, *Purity and Danger: An Analysis of the Concepts of Pollution and Taboo* (London: Routledge, 1966).

<sup>7</sup> O. Bekou & T. Murphy, “Editorial” (2010) 10 Human Rights LR 597-599, at 597.

<sup>8</sup> R. Williams, “Public Choice and Social Learning: The New Multimedia Technologies in Europe” (2000) 16 Information Society 251-262. Conversely, some technologies accompanied by anticipation and hype amounted to very little (eg: videophones and video-texting).

<sup>9</sup> For example, consider the internet and file-sharing and its ongoing destabilisation of the music industry: P. Alexander, “Peer-to-Peer File Sharing: The Case of the Music Recording Industry” (2002) 20 Rev Ind Organisation 151-161; T. Kalker et al., “Music2Share: Copyright-Compliant Music Sharing in P2P Systems” (2004) 92 IEEE Proceedings 961-970; A. Zentner, “Measuring the Effect of File Sharing on Music Purchases” (2006) 49 J Law Econ 63-90; and others.

eminently justifiable and needs to be expanded, enhanced, and vastly improved, but equally that we must not expect too much of law.

Very briefly, we understand ‘legal foresighting’ to mean the identification and exploration of possible and desirable future legal or quasi-legal developments aimed at achieving valued social and technological ends. It is a fundamentally active and outcome-oriented reformative process; while it offers us the opportunity to subject technological trajectories, social trends, and legal conditions, inertias, and developments to early, rational, contemplative reflection, it is its shaping capacity that makes it valuable. Legal foresighting should help us *create* pathways into the unknown,<sup>10</sup> and part of that creation may mean (or demand) a fundamental re-visioning of the legal setting itself, its instruments, institutions, and regulatory or governance mechanisms. We must be prepared to ask whether existing systems (and their assumptions and values) are capable of responding to the demands being made of them and of delivering the future that we want.

As should be clear, this paper, and indeed the act of legal foresighting is concerned with law in society, and with making the law more effective in its social operation and in its relationship with the object of its attention – dynamic, complex and uncertain science. It offers a framework for performing legal foresighting in the face of new and emerging technologies, drawing in particular on the authors’ experience in the bioscience and biotechnologies context.

The paper is divided into four parts. Part I considers the evolution and uses of foresighting techniques in the context of technological innovation. It outlines the history and relevance of the approach, while acknowledging its limitations as identified in non-legal disciplines. Notwithstanding, Part II mounts a defence of foresighting in the legal context, arguing that it should be a non-negotiable element of regulatory preparedness for new and emerging technologies. Part III offers an entirely novel framework to carry out legal foresighting. It describes not only the range of considerations to be taken into account but also offers a 3-D matrix of elements which, together, embody a generic method for legal foresighting that is applicable to any type of new technology or innovation. This includes the need to challenge our assumptions about the advent of any given technology and also a means to determine whether and how law might have a role to play in the promotion of a particular technology trajectory. Finally, Part IV considers how foresighting might work in practice. It draws on examples from the authors’ experiences and suggests how our foresighting model could be deployed to improve societal preparedness in these and numerous other cases.

## **Part I: THE EVOLUTION AND USES OF FORESIGHT**

It was not until the 1980s that active ‘foresighting’ exercises emerged as regular and formal policy tools, and they did so in the technology sphere. Such exercises were frequently seen as a means to encourage networking and new partnerships, and to predict medium and long-term science, technology, and innovation trajectories so that investment of public funds could be strategically managed.<sup>11</sup> Unfortunately, and perhaps predictably given the changing and ever more complex nature of modern

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<sup>10</sup> For an early seminal work see B. Wynne, “Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventive Paradigm” (1992) 2 *Glob Environ Change* 111-127.

<sup>11</sup> B. Martin & J. Irvine, *Research Foresight: Priority Setting in Science* (London: Printer, 1989), L. Georgiou, “The UK Technology Foresight Programme” (1996) 28 *Futures* 359-377, and K. Cuhls et al., *DELPHI '98 – Studie* (Karlsruhe: Fraunhofer ISI, 1998).

technologies, these exercises frequently failed to deliver. One contributor to this failure was that forecasters and policymakers assumed a linear innovation process in which advances are driven by incremental increases in technical knowledge generated by public research which is then transferred to private industry which transforms that knowledge into useful products disseminated through the marketplace; where practices failed to map onto this model, they assumed a failure or mutation of the field studied rather than a problem with the model itself.<sup>12</sup>

Foresighting failures prompted a deeper reflection on, and study of, the foresighting process in se. These methodological studies, combined with substantive foresight activities, led to an evolution of foresighting as an exercise. Modifications, which were incorporated gradually and unevenly, included an increase in attention to socio-economic dimensions, a broadening of the exercise to include identification of undesirable impacts and trajectories, and a greater role for diverse stakeholders (which itself encouraged stakeholders from science and industry to network better).<sup>13</sup> New frameworks and a range of methodologies (eg: scenarios, relevance trees, benchmarking, critical technology exercises, multi-criteria analysis, and DELPHI) led to more nuanced understandings of science and research trajectories.<sup>14</sup> As a result, assessors slowly shifted from linear conceptions to more complex and interactive ones which better reflected the actual interplay between actors and the unpredictability of innovation outcomes.<sup>15</sup> Throughout, however, and despite the recognition of greater contingency, complexity, and dynamism, the central focus remained on science, technology, and industry.<sup>16</sup>

Eventually, and again unevenly, actors came to understand that technology was shaped by much more complicated innovation processes and organisational practices than previously modelled.<sup>17</sup> They also came to understand that technology is not the only driver of change, but is simultaneously an object being driven, and so had to be ‘problematised’ (i.e. questioned from a definitional and scope perspective and made the subject of investigation) in the same manner that ‘innovation’ was problematised, and that ‘society’ was problematised in other settings.<sup>18</sup> The fact that technology is recognised as having a social role means that both factors – technology and society – have to be understood as *co-producing* our reality and as objects of equal contingency and social construction<sup>19</sup> (albeit that actors are only beginning to integrate the key aspects of technology [and its supporting systems] and society as

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<sup>12</sup> J. Tait & R. Williams, *Integrating Technological and Social Aspects of Foresight in Europe*, 2003, Final Report of the ITSAFE Project, available at [http://www.supra.ed.ac.uk/Publications/ITSAFE\\_FINAL\\_REPORT.pdf](http://www.supra.ed.ac.uk/Publications/ITSAFE_FINAL_REPORT.pdf) [accessed 7 April 2009].

<sup>13</sup> *Ibid.*, and K. Menrad et al., *Future Impacts of Biotechnology on Agriculture, Food Production and Food Processing – A Delphi Survey* (Heidelberg: Physica-Verlag, 1999).

<sup>14</sup> These methods are explored in S. Faucheux et al, *Annex 4: Integrating Technical and Social Aspects of Foresight in Europe – The Environment Dimension*, Final Report of the ITSAFE Project, available at <http://www.supra.ed.ac.uk/Publications/annex4.pdf> [accessed 8 April 2009].

<sup>15</sup> J. Tait & R. Williams, *supra*, note 12, and S. Russell & R. Williams, “Social Shaping of Technology: Frameworks, Findings and Implications of Policy” in K. Sørensen & R. Williams (eds), *Shaping Technology, Guiding Policy: Concepts, Spaces and Tools* (Aldershot: Edward Elgar, 2002) 37-132.

<sup>16</sup> J. Tait & J. Chataway, “The Governance of Corporations, Technological Change, and Risk: Examining Industrial Perspectives on the Development of Genetically Modified Crops” (2007) 25 *Enviro & Planning C* 21-37.

<sup>17</sup> J. Tait & R Williams, *supra*, note 12, at 17.

<sup>18</sup> M. Jørgensen et al., “The Social Shaping Approach to Technology Foresight” (2009) 41 *Futures* 80-86.

<sup>19</sup> *Ibid.*

equal factors for study).<sup>20</sup>

Importantly, while law and legal matters often form part of the deliberations, actors only rarely explicitly reflect on the appropriate or optimal role of law as a component of this dynamic, despite the fact that the solutions that may present will almost inevitably involve the law in some form or another.<sup>21</sup> This could involve, for example, the need for the law to legitimise or ‘enable’ the technology through novel regulatory regimes or, where it is thought necessary, to limit or prohibit the technology. Softer law options must also be considered, such as codes of conduct and professional guidance. A further and final crucial factor that was identified early in this period was the so-called ‘Collingridge dilemma’<sup>22</sup> that is faced by regulators and legislators alike: at what point in the development of a technology should regulation or law intervene? To intervene too early can mean that there is insufficient, conflicting or confusing data about the nature and impact of the new technology to act effectively; to wait too long can mean that the technology has become entrenched in a particular social context, and influence and change become correspondingly more difficult to effect.<sup>23</sup>

All told, we enter the second decade of the twenty-first century with a more socially grounded and solution-seeking form of foresighting solidly embedded in many elements of technological and social questioning, often undertaken within the context of specific societal problems and demands such as disease prevention, aging and disease, healthcare environment needs, etc.<sup>24</sup> Indeed, the range of, and importance attached to, the foresighting being pursued has created a pressure for countries and other actors to foresight just as a means of ‘staying modern’, particularly in the life sciences fields. However, given the signal failings of the law in predicting future social or technological outcomes,<sup>25</sup> one might ask: (1) Should we undertake such

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<sup>20</sup> For more on the early stage nature of this integration, see T. Reiss & O. Strobel, *Annex 3: Integrating Technical and Social Aspects of Foresight in Europe – State-of-the-Art Report: Life Sciences*, Final Report of the ITS SAFE Project, available at <http://www.supra.ed.ac.uk/Publications/annex4.pdf> [accessed 8 April 2009].

<sup>21</sup> Arguably, an example of this is the stem cell research setting which, in some cases/jurisdictions, called upon the law too early. For example, in Canada there was a stem cell law before there was much domestic stem cell research. While this is not necessarily anathema, the unreflexive deployment of the law can, and in Canada did, shape *and limit* the parameters of the debate, not just the legal debate, but the full ethical-legal-social debate.

<sup>22</sup> D. Collingridge *The Social Control of Technology* (London: St Martin’s Press, 1982).

<sup>23</sup> An obvious example of the first phenomenon – legislating too early – is the attempt to ban ‘cloning’ in the UK through the *Human Fertilisation and Embryo Act 1990*. An example of the latter instance – waiting too long – is the failure to legislate to facilitate the use of medical records for research, which seriously restricts (or complicates) research possibilities and which, by default, relies, improperly, on the extension of the consent paradigm in that field.

<sup>24</sup> T. Reiss & O. Strobel, *supra*, note 20. An example of such a study is the German Future Process: K. Cuhls et al., *The German BMBF Foresight Process, EFP Brief No. 174* (2010), available at <http://www.foresight-platform.eu/wp-content/uploads/2011/01/EFP-Brief-No.-174-German-BMBF-Foresight.pdf> [accessed 30 March 2011]. For more on foresight in the UK, see <http://www.foresight.gov.uk/index.asp>. For examples of foresighting in the health setting, see J. Tait et al., *Infectious Disease: Preparing for the Future – Risk Analysis* (London: Office of Science & Innovation, 2006), available at <http://www.foresight.gov.uk/Infectious%20Diseases/t2.pdf>, and S. Hay et al., *Infectious Disease: Preparing for the Future – Population at Malaria Risk in Africa 2005, 2015, 2030* (London: Office of Science & Innovation, 2006), available at [http://www.map.ox.ac.uk/PDF/T8\\_2\\_foresight.pdf](http://www.map.ox.ac.uk/PDF/T8_2_foresight.pdf).

<sup>25</sup> One example of this is the furore surrounding, and flurry of activity aimed at, predicting the process of, and then preventing, human reproductive cloning, a procedure that was much legislated, domestically and internationally, but never truly in the minds of serious researchers as a scientific pursuit.

exercises in the legal setting? and (2) How might effective and justifiable processes be structured and managed to perform this task? These questions are addressed in the following sections.

## **PART II: SHOULD WE FORESIGHT IN THE LEGAL SETTING?**

### **Pitfalls and Antipathies to Legal Foresighting**

At the outset, we must acknowledge the myriad challenges of, and hurdles to, effective foresighting. It is a positively fraught process, riddled with stakeholder tensions, evidentiary lacunae, disciplinary and subject insularism, unanticipated consequences, false horizons, and so on. Common pitfalls include misunderstanding the nature and potential contribution of emerging technologies, misconceiving the trajectory of current scientific or social trends, and failing to predict pivotal but unanticipated innovations or social events.<sup>26</sup> Obviously, then, when embarking on any foresighting endeavour, one must begin from a position of caution and humility, a fact most precisely and amusingly articulated in the following:

I have accepted an invitation to predict the regulatory future of securities markets in the United States. My acceptance is foolish for so many different reasons that I despair of counting them all. I therefore draw attention to two of the predictions I am about to offer and trust that the reader will overlook all the others. My first prediction is that my predictions will be proven wrong. My second is that having this essay appear in print is a big mistake. A printed essay creates an irrefutable record that will memorialize the stunning accuracy of my first prediction. On the brighter side, the record will then reflect that I knew that I had no chance of getting it right.<sup>27</sup>

In short, there are personal and professional pitfalls to foresighting. One must appreciate that technology, society, and the law can end up going in completely different directions and to completely different places than originally imagined or expected in the foresighting process. For that reason, foresighting has been described as a *resource* for reflexive analysis rather than as a means of devising durable plans of action for, or infallible maps into, the future.<sup>28</sup>

We must also acknowledge the general antipathy of the law (and judicial decision-making in particular) toward hypotheticals, with which the foresighting exercise is obviously closely associated. One wonders if this antipathy has contributed to the relative dearth of useful foresighting in the legal setting; for without a doubt foresighting has been positively rare, and generally poorly executed. By way of example, consider the state of ‘foresighting’ in the intellectual property context:

- In 2004, Dr. Francis Gurry, then Deputy Director General of the World Intellectual Property Organization (WIPO), admitted that the WIPO had ‘no

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<sup>26</sup> R. Williams, “Compressed Foresight and Narrative Bias: Pitfalls in Assessing High Technology Futures” (2006) 15 *Science as Culture* 327-348, and W. Roth, “Radical Uncertainty in Scientific Discovery Work” (2009) 34 *Science Tech Human Values* 313-336.

<sup>27</sup> J. Grundfest, “The Future of United States Securities Regulation: An Essay on Regulation in an Age of Technological Uncertainty” (2001) 75 *St Johns LR* 83-111, at 83.

<sup>28</sup> See J. Tait & R Williams, *supra*, note 12, at 19.

methodology whatsoever’ for tackling the interface between its specialised field, and patent law in particular, and broader public policy, which would include health and life science policy.<sup>29</sup>

- In 2007, the European Patent Office (EPO) undertook its ‘Scenarios for the Future’ exercise,<sup>30</sup> but a close examination of the resultant report suggests that this was more a rediscovery of known factors that may impact on the future rather than a theorising and formalising of mechanisms to support actors in actively shaping the future.<sup>31</sup>
- In 2008, the EPO held another meeting, this one called ‘Patents to Save the Planet’, and that exercise failed to adopt the lesson learned in the technology context years before, namely that innovation is a complex and non-linear (non-push/pull) milieu; it assumed, and the presumption endures in the intellectual property setting, that a linear relationship exists between the patent system, invention, and successful innovation.<sup>32</sup> More devastatingly, but consistent with the previous efforts, it failed to recognise that the law is one of the elements that *must* be ‘problematized’ if foresighting is going to have any hope of optimising the legal and regulatory setting.

The upshot of the above is that, certainly in the intellectual property setting but also more broadly, ‘authentic’ legal foresighting is not only uncommon but very notable by its absence.

### **Value and Importance of Legal Foresighting**

Given the above, one might conclude that any attempt to develop foresighting methods for law would be a futile exercise or at least one bound by serious limitations. Even the utility of *trying* is open to question. We, however, are not of this view. Indeed, we are strongly of the contrary view that we are *obliged* to undertake legal foresighting exercises. Such is necessary unless we reject any significant role for law in technology development (which is inconceivable), and if we hope to keep the law relevant and just in that role (which is axiomatic). Indeed, these last two considerations are vital characteristics which grow in importance as law is increasingly relied upon as a central social shaping and integrating mechanism of the modern era.<sup>33</sup> Just as science and new technologies are dynamic and evolving spheres of human knowledge, so too must be the law if it is to provide a responsive and directive role in the management of this knowledge and associated practices.

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<sup>29</sup> Presentation at “Bioethical Issues of Intellectual Property in Biotechnology”, 6-7 September 2004, Tokyo, Japan.

<sup>30</sup> EPO, *Scenarios for the Future* (Munich: EPO, 2007), available at [http://documents.epo.org/projects/babylon/eponet.nsf/0/63A726D28B589B5BC12572DB00597683/\\$File/EPO\\_scenarios\\_bookmarked.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/63A726D28B589B5BC12572DB00597683/$File/EPO_scenarios_bookmarked.pdf).

<sup>31</sup> Recognised by G. Laurie, “Fore-Warned is Fore-Armed: Is Intellectual Property a Suitable Case for Foresight?” (2008) 39 *Int Rev of IP Comp Law* 507-510.

<sup>32</sup> Noted by G. Laurie, *ibid*, who reports that the meeting explored options for reforming the patent system to better support green innovation.

<sup>33</sup> So claimed by J. Habermas, *Between Facts and Norms* (Boston: MIT Press, 1996). And the human rights paradigm is emerging as the dominant discursive paradigm: R Ashcroft, “Could Human Rights Supersede Bioethics?” (2010) 10 *Human Rights LR* 639-660, and A. Plomer, *The Law and Ethics of Medical Research: International Bioethics and Human Rights* (London: Cavendish, 2005).



The importance of foresighting, indeed of socio-legal-ethical contemplation more generally, is exemplified by the following:

Working towards biosensors for diagnostics, and towards passive and active drug delivery systems, as well as their combination (theranostics) is an important activity ... [w]hen asking R&D people in Philips Company (for which new diagnostic tools are one of their strategic directions) about societal impacts like changing responsibilities when point-of-care diagnostics become widespread, they said that was not their business. 'Others should look into it' – at some later time, but then the parameters of the situation may have been fixed already by the shape the technology has taken. For the Philips people, this is a matter of pragmatic negligence, and the hope that others will be diligent. At the societal level, it amounts to organised irresponsibility. When this is made explicit and debated, perhaps contended, there will be a struggle about new roles and responsibilities, and of distributing praise and blame (before the fact).<sup>34</sup>

Issues of roles, responsibilities, and blame are integral concerns of the law; they are precisely the issues that law is often called upon to address and delineate when regulating science and new technologies. As such, it is hard to see how legal foresighting is any less important, or essential, than social or innovation foresighting. Indeed, the importance of considering a role for the law (and of traditionally political and legal concepts and practices) to the science and technology setting is emphasised by the injection of political and democratic practices into the governance of science:

The complexity resulting from the mixing of science and the rules that govern civil life give rise to concern about the most adequate ways of governing science in democratic societies, and lead to rethinking the idea of the state under the rule of law ...<sup>35</sup>

What is less well considered is the precise *nature* of the role that the law can and should play. For example, we should not imagine that hard law options – driven or imposed by the state alone – are the only, or the best, shapers of technology trajectories or innovation and research practices. As Scharpf points out:

Much effective policy is produced not in the standard constitutional mode of hierarchical state power, legitimated by majoritarian accountability, but rather in associations and through collective negotiations with or among organizations that are formally part of the self-organization of civil society rather than of the policy-making system of the state.<sup>36</sup>

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<sup>34</sup> T. Swierstra & A. Rip, "Nano-Ethics as NEST-Ethics: Patterns of Moral Argumentation About New and Emerging Science and Technology" (2007) 1 Nanoethics 3-20, at 18.

<sup>35</sup> M. Tallacchini, "Before and Beyond the Precautionary Principle: Epistemology of Uncertainty in Science and Law" (2005) 207 Tox Applied Pharmac S645-S651, at S646.

<sup>36</sup> F. Scharpf, *Games Real Actors Play: Actor-Centred Institutionalism in Policy Research* (Boulder: Westview, 1997), at 204.

This suggests that law might play less of a legislatively grounded normative role (via legislation and regulation-based rules) and more of a space-creating and context-shaping role that permits more in the way of self-help or self-regulation at a grass-roots level by actors responsible for the development and adoption of technological advances.<sup>37</sup>

In fact, the recognition that different (and non-traditional) types of legal interventions might be desired and/or warranted means that we must, at the outset, have a clear conception about both the modes of law that are available and the ultimate aim(s) of their deployment. In other words, we must always remain cognizant of, first, what the law is likely to be called on to do, and, second, what we want to achieve through the law (possibly above and beyond that pragmatic call). This requires us to decide, from a theoretical perspective, whether the law is an enabler or a prohibitor of technologies. The former, which adopts an expansive view of the possible role of law, might give the law more to do, or, if silence is deemed best to allow the technology to develop, much less to do; the latter is a common role that often undergirds both a cautious approach toward technologies and a conservative approach toward the role of law. In any event, the point is that one must take a position on what social role the law should or can perform (ie: what will the law in society do?).

This question will depend on the context, and it may also depend on who is involved in answering the question. Obviously, a wide range of actors are implicated in the technologies fields, and so a wide range of stakeholders appropriate to the legal foresighting exercise also emerges. With this realisation comes a wider sense of how 'law' might be considered as part of any given technology trajectory. As demonstrated, however, foresighting efforts in the legal sphere – narrowly or widely defined – have, to date, been too few, and all-too-frequently too impoverished. Renewed efforts must be made and new frameworks need to be fashioned which accept that, while technological and social trends often precede hard law interventions, rule-based conduct - through legitimate foresighting - *can* be more proactive and creative at all stages of development, and *can* illuminate and encourage new pathways of action.<sup>38</sup> It does not follow, however, that methods of foresighting for law should necessarily follow or adopt methods used in other spheres. This acknowledgement requires us to define more precisely and offer a framework for legal foresighting as we conceive the practice.

### **PART III: HOW SHOULD WE FORESIGHT?**

We have already offered a definition of what legal foresighting is, but of course, that is not enough. We cannot really answer the 'what' without answering in some detail the 'how'. Legal foresighting can be helped or hindered, enriched or impoverished, justified or undermined by the frameworks and procedures/methods on which it relies, as well as by the institutional limitations (or blinders) that it fails to recognise or

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<sup>37</sup> See, for example, A. Rip, "De Facto Governance of Nanotechnologies", in M. Goodwin, B-J. Koops and R. Leenes (eds.), *Dimensions of Technology Regulation* (Nijmegen: Wolf Legal Publishers, 2010) 285-308.

<sup>38</sup> In this regard, we draw attention to the efforts of SCRIPT, the AHRC Centre for Research in Intellectual Property and Technology Law, University of Edinburgh. In an attempt to begin to fill the lacunae, it has formed regulatory foresight fora in the medical, intellectual property, and information technology governance arenas. In each case, the forum is intended to serve as a flexible, interdisciplinary vehicle for enriching existing and emerging processes of policy and technological contemplation: see <http://www.law.ed.ac.uk/ahrc/>.

overcome. We are concerned here with offering a framework that facilitates the effectiveness and utility of foresighting with respect to law and legal responses. That is, we are concerned with how to better design systems – using law or quasi-legal mechanisms – that increase the chances of individuals and institutions approaching future challenges from the best possible starting point and taking into account the full scope of relevant considerations in a timely and appropriate manner. The essential question *about* law is how it might be best deployed towards these ends. In other words, we are concerned with the reflexive approach deployed in the foresighting exercise by its designers and/or participants; we are less concerned to prescribe any specific methodology. Indeed, different methods will likely be required for different foresight exercises. Equally, as noted above, different deployments of law (i.e. law in various guises) will be possible. The following section offers an initial starting position which is composed of two core features: (1) five foundational considerations; and (2) one three-dimensional master matrix. These are further extrapolated below.

### **(1) Five Foundational Considerations**

We begin our analysis of a legal foresighting framework by highlighting five critical considerations that must serve as points of departure; these are five understandings (i.e. world views and methodological assumptions or tenets) that must be appreciated or accepted at the outset and somehow incorporated or made an explicit part of the process. The five foundations are: (i) fundamental imperatives; (ii) socio-technical complexity; (iii) scope-relevant assumptions; (iv) divergent cultures; and (v) the role of risk/precaution. Each of these will be briefly addressed below.

#### *(i) Fundamental imperatives*

First, in foresighting exercises and indeed more generally, certain imperatives are often taken as axiomatic. In the biotechnologies setting, with which we are primarily concerned and on which we rely as a case study, the following imperatives are frequently offered, and colour all else, namely that:

- health technology and healthcare innovation should produce effective outcomes supportive of the public good and that are responsive to regional and global health needs;
- technological change, social needs, and regulatory mechanisms are all important mutually-influencing components of the modern setting (ie: they are active aspects of the subject scene which influence one another);<sup>39</sup>
- health and wellbeing are fundamental to individual and social functioning and the law's aim must be to protect and promote that wellbeing in as optimal a way as possible;<sup>40</sup>

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<sup>39</sup> See M. Smith & L. Marx, *Does Technology Drive History?* (Cambridge: MIT Press, 1998), who question technological determinism and take a more nuanced view of technological development.

<sup>40</sup> This is supported by all manner of legal theorists, including R. Dworkin, *Taking Rights Seriously* (Cambridge: Harvard U Press, 1978), J. Raz, *The Morality of Freedom* (Oxford: Clarendon Press, 1986), A. Sen, *Development as Freedom* (Oxford: OUP, 1999), J. Ruger, "Ethics and Governance of Global Health Inequalities" (2006) 60 *J Epidemiology Community Health* 998-1003, N.

- it is valuable and important for the law not just to set boundaries but also to promote science, technology, and healthcare innovation in a more positive way, particularly where they enhance individual and public health and related public goods, and despite enduring questions over what counts as public goods and who determines this (ie: law has a positive social shaping role aimed at encouraging just outcomes);<sup>41</sup> and
- responsive and timely innovation can be encouraged by creative and sensitive governing institutions and instruments, normally through law or other legal mechanisms which take the guise of regulatory or governance arrangements.<sup>42</sup>

While we take these assumptive imperatives to be correct and appropriate, it is nonetheless important to examine and re-examine them within the foresighting exercise, which must also integrate ethical, legal and social issues/concerns, and have as one of its objectives the rational restructuring of the socio-legal (as opposed to merely the innovation or policy) environment.

#### (ii) *Socio-technical complexity*

Second, reality is much more complex and dynamic than any imagining of any single foresight exercise. Even with an inclusive approach that draws on diverse stakeholders, we can predict only a part of the reality that will be relevant to the socio-technological evolution for which regulation or governance might be sought (short of time-intensive and finance-devouring systems-wide empirical foundations, which even then might fail to offer all the evidence one might like or need). In short, we must necessarily work from partial knowledge and on an unknowable timescale. But that partial knowledge must not stem from ignorance or a wilful blindness toward reality. The foresighting exercise, whatever methodology is used, must acknowledge and engage with the fact that the future will be linked-up and networked: public health, to bio-economies, to innovation frameworks and loops, to legal regulatory mechanisms, to political-economy movements, and so on. One must account for globalisation and interconnectedness across field, discipline, geography, ethnicity, etc., and one must be aware that pressures and actions in one field, even though seemingly distant, can have profound impacts on that being studied.

In the life science setting, it is important to be aware of the following defining features:<sup>43</sup>

- Life science technologies and processes are enabling and have implications for a wide range of industrial, commercial, and social sectors in different ways and at different times (i.e. compare technology development with technology

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Daniels, *Just Health: A Population View* (Cambridge: CUP, 2008), and N. MacCormick, *Practical Reason in Law and Morality* (Oxford: OUP, 2008).

<sup>41</sup> The positive potential of law is recognised in J. Somsen, *Regulating Modern Biotechnology in a Global Risk Society* (Amsterdam: Vossiuspers UvA, 2004), who argues that the law has a key role to play in ensuring that biotechnology turns out to be a blessing and not a curse.

<sup>42</sup> The importance of regulation to innovations in the construction sector are noted in P. Dewick & M. Miozzo, "Sustainable Technologies and the Innovation-Regulation Paradox" (2002) 34 *Futures* 823-840.

<sup>43</sup> J. Tait & R Williams, *supra*, note 12, at 20.

adoption with widespread technology use);

- There is a close link between basic research and industrial utilisation, but a long period before practical applications become available to consumers, although this can also be sector-specific (i.e. compare digital innovations - where the gap between problem and solution is very narrow - and biotechnological solutions, where the ‘distance’ and timelag from bench to bedside is often considerable);
- Different sectors (public and private) might differentially control large portions of the knowledge base at different times and in different geographical locations (i.e. compare Europe and the United States); this has implications for the value and interest-based positions which might be brought to bear on technologies and practices, including legal practices<sup>44</sup>; and
- Given their concern with understanding and modifying (human) life, the life sciences continuously raise ethical and social issues even as they resolve others.<sup>45</sup>

A foregrounding and appreciation of these realities together with the complex, fluid, and global nature of modern practices will enhance the quality of the foresighting activity and its outcomes. As a minimum, it will be essential to identify the key stakeholders, their interests, and their value positions. This understanding is crucial to any effective foresighting exercise because of the considerable influences these factors can have on the social understanding (e.g. hype or fear), the mobility, and the broad trajectory (or outcome objectives) of any given technology.<sup>46</sup>

### (iii) *Scope-relevance assumptions*

Third, while the particular methodology adopted within the foresighting exercise(s) might vary, there are certain assumptions (i.e. certain matters accepted as fact and other matters rejected as unfounded) that are supported by evidence and (our) experience that are properly built-in to the undertaking. They are as follows:

- We assume that technological change, social needs, and regulatory mechanisms are all important change factors and are all mutually-influencing components of our reality (ie: they are fluid and dynamic aspects of the subject setting which influence one another).
- We reject the proposition that any element of the existing legal regime is or should be sacrosanct (absent fundamental rights), or necessarily fit for purpose

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<sup>44</sup> See G. Laurie, A. Bruce & C. Lyall, “The Roles of Values and Interests in the Governance of the Life Sciences: Learning Lessons from the ‘Ethics+’ Approach of UK Biobank” in C. Lyall et al. (eds.), *The Limits to Governance: The Challenge of Policy-Making for the New Life Sciences* (Aldershot: Ashgate, 2009) 51-78.

<sup>45</sup> And there is a relationship between the perceived controversy of a technology or issue and the extent to which socio-economic and technological integration is seen as relevant: K. Menrad et al., *supra*, note 13.

<sup>46</sup> Some of this preliminary work has been conducted in Argentina through the GET: Social Values Project: see <http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/> and the outputs identified.

to respond to technological advances; in the main, existing legal approaches are subject to amendment.

- We eschew the contemplation of *possible* Frankenstein futures which are driven by ‘speculative ethics’<sup>47</sup> or media hype and which distract from the core task at hand, which is to consider how best to respond to *probable* technological futures. Rather, we rely on an examination of current legal, social, and technological conditions and probabilities, as well as on regulatory and developmental (including innovation) opportunities, trajectories, networks, and, importantly, visions. This is not to deny the considerable challenges of identifying what counts as evidence in this regard.
- We distinguish between ‘regulatory’ and ‘governance’ mechanisms as distinct socio-legal responses which rely on different conceptions of ‘law’; thus, while *regulation* will tend to be a state-driven, vertically-oriented, top-down, command-and-control deployments of formal (hard law) instruments, *governance* is a far more horizontally-oriented enterprise, more likely driven by actors involved in technology development and adoption, and more reliant on soft law options such as guidance or professional codes.
- We discern two crucial roles for the law, one being to *promote* technological development and the distribution of associated social benefits, and the other being to *protect* society from the less acceptable vagaries of new technologies. Thus, legal foresighting does not preclude the possibility that law should intervene to prevent a particular technological development or at least carefully restrict its trajectory, but, as further elaborated on in foundation five below, we do not advocate that a risk-based assessment towards new technologies should necessarily be a defining or determining feature of legal foresighting.

(iv) *Divergent cultures*

Fourth, law and science have very different cultures, and this must be consistently born in mind, particularly when contemplating evidence from different stakeholders. For example, science is very much about future imaginaries based on newly-established certainties (which may nonetheless prove false); it is about destabilising past assumptions and forming new ones, creating novelty, founding proofs of principle and uncovering facts that are verifiable and reproducible. Scientific findings are expected to be taken up now and in the future so that something may be ‘built toward’ down the road.<sup>48</sup> Conversely, law is much more grounded in the past and present; legislation tends to be framed by problems that have arisen rather than those that might arise; case law (judge-made law) can only be decided on the basis of past precedent and the facts presented before a court. Rules of all kinds are open to interpretation and manipulation. Certainty is elusive and relative. The consequence of all of this is that different values and principles are paramount in the respective domains. Thus, for example, science values freedom of research, inquisitiveness,

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<sup>47</sup> A. Nordmann, “If and Then: A Critique of Speculative NanoEthics” (2007) 1 *NanoEthics* 31-46, and A. Nordmann & A. Rip, “Mind the Gap Revisited” (2009) 4 *Nature Nanotech* 273-274.

<sup>48</sup> T. Swierstra & A. Rip, *supra*, note 34.

integrity and collegiality, so as to encourage blue skies thinking and experimentation. Law values clarity and compliance and favours conservative and incremental development; it tends to set boundaries rather than break them down.

Additionally, these fields often have very different scopes of perspective. Though studies indicate that innovation is subject to complex contingencies characterised by interaction, serendipity and dynamism,<sup>49</sup> science as a pursuit is typically concerned with a specific question in a specific context, and less so about the social implications of the answer to that question.<sup>50</sup> Conversely, the law must concern itself more regularly with all of society; it is aimed at organising and regularising social relationships and interactions through the extension of, and limitations on, rights. In pursuing that aim, calls have been made for the law (and regulatory efforts) to adopt a deeper appreciation of technology,<sup>51</sup> and that must be taken on board if the foresighting exercise is to bear fruit. We contend, however, that the same must be true of science with respect to law, if its contributions are to find a suitable place in societies built around architectures (and regulations) framed by law. Despite these cultural differences, however, it is important to recall throughout that both cultures are socially constructed, and therefore subject to influence and change.<sup>52</sup> In short, culture-cognizance is important but culture-constraint need not be accepted. The overarching lesson must be that the *co-production* of regulatory or legal responses to scientific developments is the most desirable and optimal approach and that this must feature in any (legal) foresighting exercise. To consider once again the bare minimum, this implies that stakeholders from the totality of relevant cultures must be engaged throughout the process.

#### (v) *The role of risk/precaution*

Fifth, and vitally important, legal foresighting must be much, much more than a risk assessment. All too often foresighting exercises, regardless of the setting, but particularly in the technology setting, dwell on, and therefore get mired in, matters of risk (environmental, social, communal, individual). The result is that foresighting exercises become precautionary exercises focusing on risk management debate and design. This collapsing of categories must be avoided at all cost. Risk concerns in the environmental setting gave rise, in the 1970s, to the ‘precautionary principle’.<sup>53</sup> Definitions of the principle abound, but it is generally taken to mean that lack of scientific certainty must not be used as a reason to ignore or postpone preventive or remedial action where there are good reasons to act.<sup>54</sup> The following definition clearly reflects its relationship to prevailing conditions of social complexity and scientific uncertainty:

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<sup>49</sup> See J. Tait & J. Chataway, *supra*, note 16, and R. Williams et al., *Social Learning in Multimedia: Final Report to European Commission*, DGXII, Edinburgh, 2000.

<sup>50</sup> A fact well illustrated by the quote above from T. Swierstra & A. Rip, *supra*, note 34.

<sup>51</sup> J. Grundfest, *supra*, note 27.

<sup>52</sup> In this regard note the questioning of the arguably manufactured scientific culture encapsulated by the so-called ‘republic of science’ advanced by Polanyi (1962) and Merton (1968) and off-claimed since: S. Jasanoff, *Science at the Bar* (Cambridge: Harvard U Press, 1995).

<sup>53</sup> For the development of the precautionary principle, see A. Jordan & T. O’Riordan, “The Precautionary Principle: A Legal and Policy History” in M. Martuzzi & J. Tickner (eds.), *The Precautionary Principle: Protecting Public Health, the Environment and the Future of our Children* (Copenhagen: WHO, 2004) 31-48.

<sup>54</sup> The precautionary principle is defined in Article 174 of the Amsterdam Treaty of the European Union (1992), Principle 15 of the Rio Declaration on Environment and Development (1992), and many other instruments.

The PP provides justification for public policy actions in situations of scientific complexity, uncertainty and ignorance, where there may be a need to act in order to avoid or reduce potentially serious or irreversible threats to health or the environment, using an appropriate level of scientific evidence, and taking into account the likely pros and cons of action and inaction.<sup>55</sup>

So defined, the relevance of the precautionary principle to the technological and public health (and wellbeing) setting, and therefore to law, and indeed to legal foresighting, cannot be denied.<sup>56</sup> In fact, it is much emphasised by the following, which also highlights the above-mentioned need to make decisions on partial knowledge:

Contemporary scientific knowledge is characterized increasingly by uncertainty. This is due not only because both the risks and the unpredictability linked to it are increasing, but above all because of the intrinsic incompleteness and indeterminacy of scientific knowledge compared with the needs to make social choices, public policy, and legal decisions.<sup>57</sup>

However, to reiterate, legal foresighting in the techno-science arena must go beyond risk and precaution for the very simple but crucially important fact that the exercise is as much about *promoting* future interests as it is about *protecting* current (or future) interests. This role is supported by our appeal to the belief that ethically sound science is a public good and should be supported through social mechanisms such as law. Precautionary approaches allow us to move forward cautiously; legal foresighting must do this and more because it must enable use to move forward boldly, when it is thought appropriate to do so. This is not to deny a role for precautionary approaches in legal foresighting; indeed, quite the opposite is true. Legal foresighting has the twin objectives of asking how the law might *both* protect and promote individual and societal interests. As such, it is concerned with assessment of a role for law *both* with respect to risk *and* regulation. The former is a natural and logically prior step in any foresighting exercise – unacceptably risky technological developments cannot be allowed to proceed. Having cleared this hurdle, however, the promotional role of law falls to be considered, and more particularly whether a hard law regulatory approach or a more soft law governance approach might be most suitable with respect to the technology under scrutiny.

## (2) A 3-Dimensional Master Matrix

We now consider how this assessment might be conducted, and offer some thoughts on how law might be deployed. To that end, this section offers a three-dimensional

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<sup>55</sup> WHO, *Dealing with Uncertainty* (Copenhagen: WHO, 2006), at 3.

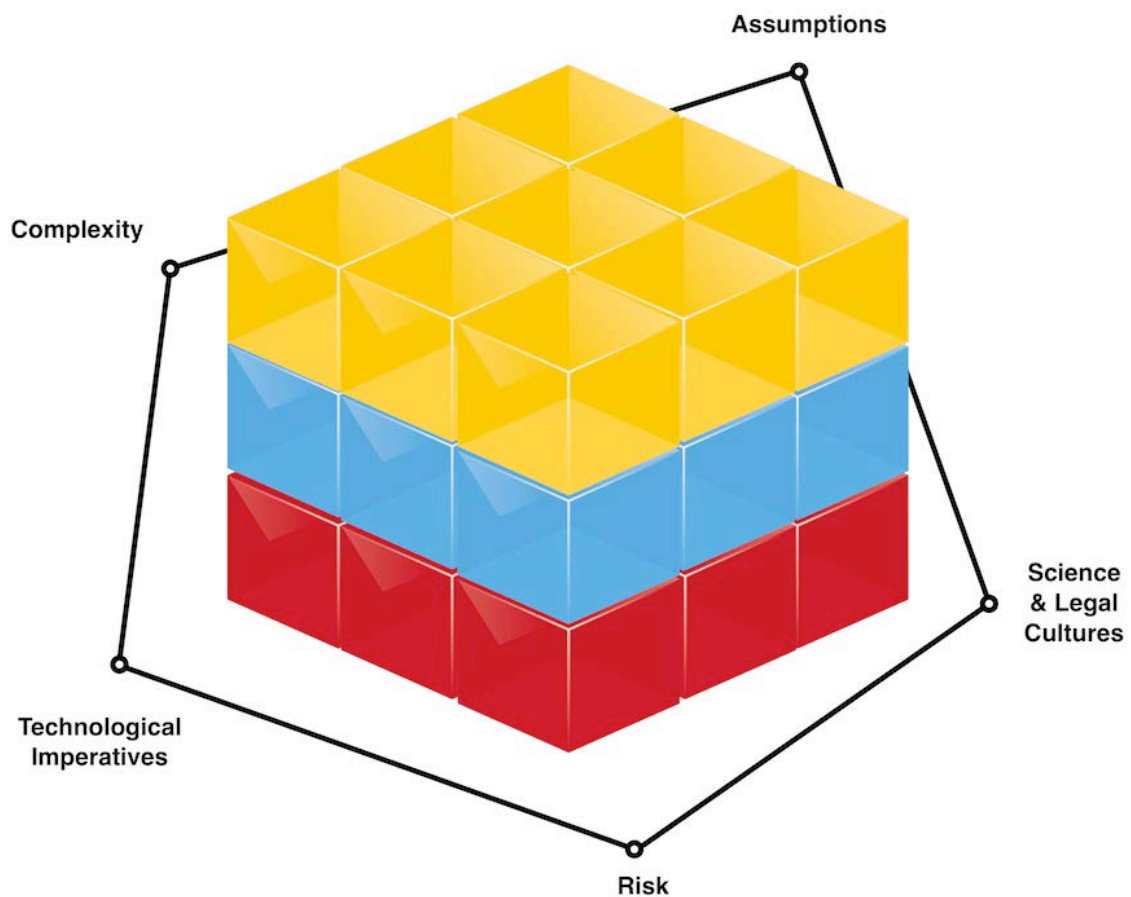
<sup>56</sup> And the case for this is made by D. Kriebel & J. Tickner, “Reenergizing Public Health Through Precaution” (2001) 91 Am J Pub Health 135-1355, and M. Martuzzi, “The Precautionary Principle: In Action for Public Health” (2007) 64 Occup Environ Med 560-670, who lament the all-too-frequent negative perceptions of the principle, usually as a result of reactionary approaches rather than true precautionary approaches to decision-making.

<sup>57</sup> M. Tallacchini, *supra*, note 35, at S647.



matrix for conducting legal foresight exercises. This matrix sits astride the five considerations outlined above. While they provide the foundation for the foresight exercise, the matrix provides the means to carry it out for any given technology or innovation. Each dimension of the matrix performs a different function. The first dimension is concerned with challenging assumptions about the ways new technologies impact on society. Its three strata provide an organised way of tackling the issues to be addressed. The second and third dimensions construct an adaptable framework of elements that can be applied to a range of technological developments to assess whether and how law might have a role to play in the promotion of the technology trajectory. Again, the strata of each dimension provide the detail and the sequence for considering the relevant issues. Each dimension is explained further below. For an illustration of the matrix together with the five foundational considerations, see Figure 1 below.

**Figure 1: Legal Foresighting Master Matrix**



*3D Matrix - First Dimension Considerations: Challenging Assumptions*

The call for increased and improved legal foresighting is founded on the belief that regulators ought to be, and are reasonably well placed to be, ‘first movers’ and

therefore important ‘carriers of agency’.<sup>58</sup> They can and ought to be rational initiators who not only enable development *through* regulation or governance, but are able to prompt positive regulatory or governance change through participative deliberation *about* regulation or governance (which in turn brings about scientific and social change). In order to do so, they (and we) must break through the oft-repeated socio-moral-legal argument patterns around technology, which have been described as follows:<sup>59</sup>

1. The existing order is unsettled by a scientific novelty that undermines self-evident moral routines/assumptions and settled legal routines/boundaries.
2. The subject innovation is followed by debates over technological determinism (ie: the degree to which human agency can actually be achieved in the technological setting).<sup>60</sup>

The positions adopted toward the innovation, often reliant on rather stock responses, such as: novelty v. business-as-usual, wow v. yuck, and promissory v. dystopian claims and counterclaims; these are persistently consequentialist, deontological, distributive, or ‘good life’ based, but they rarely speak directly to one another.

Assumptions such as these must be uncovered and challenged at the outset of the legal foresighting exercise prompted by any new or emerging technology because, at base, we must understand what we are dealing with. Crucially, to be effective this initial stage must not give in to any hype around the possible Frankenstein futures that can be envisaged; rather it requires an evidence-based assessment of the probable and likely outcomes of a new technological development, which in itself is a considerable challenge given that we can legitimately disagree over what counts as evidence. This means that law and policy-makers should not be too hasty to act lest we over-anticipate risk and over-regulate. By the same token, we must avoid complacency about how a novel development might affect wider sensibilities. In sum, our first task in legal foresighting is to challenge the assumptions that typically accompany a new technology (including those about how law should respond, which are all too frequently polarised views that the law should prohibit or the law should remain silent). These will commonly include ethical, social and legal considerations, and they might typically reflect the following pattern:

#### Ethical Assumptions/Questions

- Is this development genuinely novel in ethical terms?
- Can it be accommodated by existing ethical paradigms?

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<sup>58</sup> A claim appropriately made by T. Swierstra & A. Rip, *supra*, note 34, who, at 8, argue that human agency can make a difference at an early stage of development/innovation, when issues and directions are still unclear, but much less so in later stages when ‘alignments have sedimented’.

<sup>59</sup> For more on this pattern and the tropes relied on, see T. Swierstra & A. Rip, *ibid*.

<sup>60</sup> This delegation of agency to technology is not uncommon. Franklin has noted that Fukuyama and Habermas adopted a view of genetic manipulation as a ‘force unto itself’ and hostile to the existing social order: S. Franklin, “Better by Design?” in P. Miller & J. Wilsdon (eds.), *Better Humans? The Politics of Human Enhancement and Life Extension* (London: DEMOS, 2006) 86-94, at 87. Latour highlights the moral work performed by speed bumps and seatbelts: B. Latour, *Pandora’s Hope: Essays on the Reality of Science Studies* (Cambridge: Harvard U Press, 1999). Verbeek argues for the creation of artefacts that do moral work: P. Verbeek, “Materialising Morality: Design Ethics and Technological Mediation” (2006) 31 *Sci Tech Human Values* 361-380.

- Does it provoke a paradigm shift in our ethical stances and if so, how?

Social Assumptions/Questions

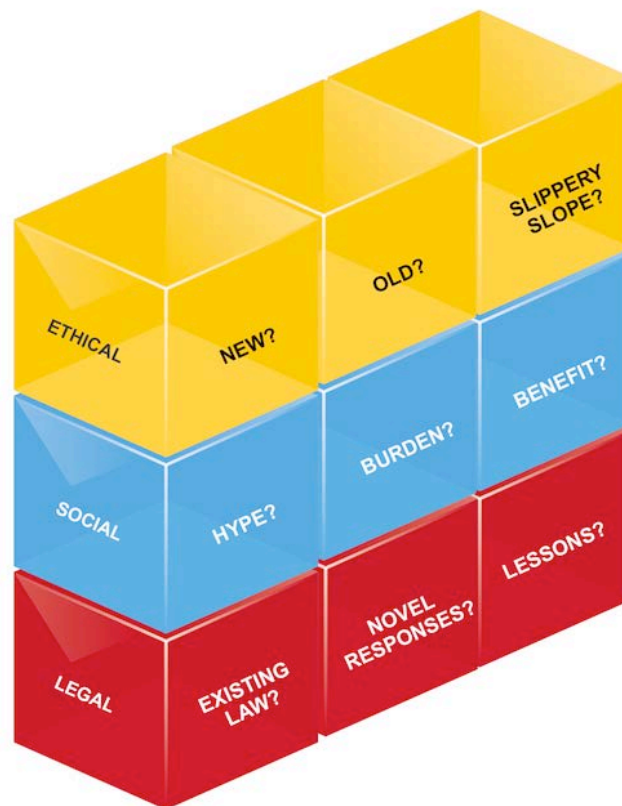
- Is this development genuinely disruptive or just suffering from hype?
- Will it disproportionately burden or alienate certain social groups?
- Will it realistically deliver benefit at acceptable cost (of whatever form)?

Legal Assumptions/Questions

- Is the development adequately covered by existing legal regimes?
- Does it raise any genuinely novel legal questions?
- Are analogous legal responses relevant here?

This first dimension of the matrix will therefore contain three strata (or rows of three boxes): ethical; social; and legal. And within each, there will be three elements (or boxes). The ethical boxes represent the key concerns of ‘new’, ‘old’, and ‘slippery slope’. The social boxes represent ‘hype’, ‘burden’, and ‘benefit’. The legal boxes are ‘existing law’, ‘novel responses’, and ‘lessons’. See Figure 2 for an illustration of this first dimension of the matrix.

**Figure 2: First Dimensions**



*3D Matrix - Second Dimension Considerations: Identifying Possible Legal Responses*

This dimension is similarly composed of three strata which, together, provide, a set of elements that build an evidence base and a solid foundation for designing effective legal responses to a new or emerging technology. The three strata address in turn: (1) pragmatic matters, (2) tolerances, and (3) the subjects of the foresighting exercise themselves.

The first stratum has to do with the pragmatic matters of the participants, the process, and the precise methodology. The designers of the foresighting exercise will have to recruit carefully and inclusively from a diverse range of key stakeholders, including regulators if they are not, in fact, the designers themselves. Stakeholder groups will obviously vary from technology to technology and issue to issue, but the following stakeholders will often be useful participants in the legal foresighting exercise: politicians, civil servants, regulators, independent policy advisors, professional bodies and learned societies, sectoral representatives, interest groups, scientists, consumers/patients, and academics. While technological and risk issues mean that the evidence base is most likely provided by experts in these fields,<sup>61</sup> assessments of the broader social, cultural, moral, and legal consequences and aims must be more inclusive.<sup>62</sup>

Thus, from a process perspective, regular and systematised communication amongst the participants must be forged. The aim is to form a durable but diverse collaborative community which has trust in and amongst its members. Of course, this requires temporal and financial commitment for the community must have a corps of repeat participants, as well as more drop-in or ad hoc and case-specific participants who assist them, or rather deliberate with them, from time to time. Public engagement exercises must necessarily be tied to the nature of technology or legal issue at hand.

Regardless of the 'type' of participant, they must be able to 'buy-in' to the exercise, which means that the procedural setting must be one of regularity and transparency. This can be facilitated by employing a range of activities. From a methodological perspective, the following practices are well theorised and well known: surveys; interviews; public discussion groups; citizens' panels/juries; consensus conferences; expert workshops; or some combination thereof. While we cannot foretell the future or the impacts of particular innovations, it has been argued that a very useful method for nonetheless trying to do so (or to prepare for uncertain futures) is the scenarios method.<sup>63</sup> The scenarios method serves two important functions: first, and not often appreciated, there is value (to the core stakeholder participants) in devising a range of scenarios with key uncertainties modified from one to the other; and second, and more widely acknowledged, there is the value (to a broader range of stakeholders) in considering the scenarios with a view to discussing the desirability (or not) of the development(s) in question, and strategising around encouraging, avoiding, or coping with the futures envisioned.<sup>64</sup>

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<sup>61</sup> So claimed by M. Ferretti, "Why Public Participation in Risk Regulation? The Case of Authorising GMO Products in the European Union" (2007) 16 *Science as Culture* 377-395.

<sup>62</sup> It has been noted that those living with the consequences of innovation must have some say in the deployment of that innovation and the future direction of related innovations: R. Sclove, *Democracy and Technology* (London: The Guilford Press, 1995); A. Feenberg, *Questioning Technology* (London: Routledge, 1999); W. Bijker, "The Need for Public Intellectuals: A Spae for STS" (2001) 28 *Sci Tech Human Values* 443-450; others.

<sup>63</sup> P. Notten et al., "An Updated Scenario Typology" (2003) 35 *Futures* 423-443.

<sup>64</sup> T. Swierstra et al., "Exploring Techno-Moral Change: The Case of the Obesity Pill" in P. Sollie & M. Düwell (eds.), *Evaluating New Technologies* (Netherlands: Springer, 2009) 119-138.

To the extent that this is a tried and tested approach, there is little reason to disturb it. This is not to claim that engagement exercises should necessarily dictate (or even strongly shape) scientific enquiry, but its importance for legal foresighting is that the imagined futures can and should include consideration of possible roles for law and legal regimes. It is here that considerations of the wide-ranging nature of law become important: What are the benefits and burdens of a top-down regulatory approach? Is this heavy-handed and restrictive of scientific freedom, or might it, in certain circumstances, give confidence and legitimacy to a scientific community to pursue their research goals and to produce quality and safe products for domestic and international markets? By contrast, might a softer law, governance approach, be more suitable for the technology in question (i.e. an approach exemplified by a grass-roots movement which steers and bolsters early developments in a scientific field but which usually provides degrees of flexibility in oversight that are not as readily available in regulatory regimes)? Either way, the scenario exercises can explore such options and a range of roles for law.

The second stratum has to do with key tolerances that must be exposed and engaged with in order for the legal foresighting exercise to deliver. By ‘tolerances’ we mean elements that are central to stakeholders’ positioning with respect to a new technology. These are issues that might operate as deal-breakers for any given stakeholder and/or as a measure of acceptance or resistance to a novel scientific development. These are often elements in policy and law making which remain implicit and under-explored. Making them explicit makes for a richer foresighting exercise and potentially a more fruitful legal response.

The first tolerance, despite our admonition above, concerns risk. Given the multiple uncertainties and indeterminacy of science, the not-infrequent lack of data to inform good policy decisions, the conflicting ways in which data can be interpreted and deployed, and the unpredictability of results, risk and precaution must form a part of the exercise and must usually feed into any regulatory options and solutions envisioned. Quite simply, in the absence of some element of risk management contemplation, some stakeholders will remain reluctant to engage. Obviously, in addition to elucidating and making sense of the innovations that are unfolding and anticipated, the scientific disciplines have something unique and important to add to the risk/precaution component of legal foresighting.

The second important tolerance that must be represented is a moral one. While moral philosophy need not necessarily rear its hidebound head, the foresighting exercise should be grounded on a strong and explicit value base. We have written elsewhere about the challenges of identifying and engaging with values.<sup>65</sup> Although the value base(s) held by certain stakeholders might be apparent from the start, this should not be assumed. Moreover, it is quite possible, and reasonable, that these value positions will be modified as the process develops and participants are invited to engage on a value-level. These defined, debated and re-defined values should form touchstones that can be used to evaluate present conditions and possible options throughout the foresighting exercise, opening up theretofore invisible possibilities for agreement and action.<sup>66</sup> The value element is additionally important because, as has

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<sup>65</sup> G. Laurie et al., *supra*, note 44, and S. Harmon, “Ethical Rhetoric: Genomics and the Moral Content of UNESCO’s ‘Universal’ Declarations” (2008) 34 J Med Ethics e24.

<sup>66</sup> For more on values found to be commonly held in the Argentine regenerative medicine context, see S. Harmon, “Regulation of Stem Cell and Regenerative Science: Stakeholder Opinions, Plurality and Actor Space in the Argentine Social/Science Setting” (2010) 2 Law, Inno Tech 95-114,

been noted elsewhere,<sup>67</sup> technological change leads to moral change, and we would argue the same about legal change (ie: that it also leads to moral change).<sup>68</sup> It has been posited that:

Policymakers can set themselves to create conditions and procedures for ... ethical controversies to unfold in a fruitful way so that they will benefit collective deliberation. ... The issue, then, is how to stimulate our *moral imagination* so as to be able to jump our 'moral shadows' as far as we can.<sup>69</sup>

The third and obviously critical tolerance represented in the foresighting exercise must concern the law itself, for it is the law and regulation that are being critiqued, probed, positioned and, ultimately, deployed. It is therefore central to this entire enterprise to examine the attitudes and expectations of all parties towards the likely role and influence of law in the innovation trajectory; is this to be largely restrictive, facilitative, top-down, bottom-up, prescriptive, enabling, nudging, or something else? Those intimately aware of the law's possibilities are essential participants in any sort of controlled speculation about its future. Having said that, care must be had not to allow the sometimes circumscribed imagination of the lawyer (as demonstrated in the intellectual property foresighting forays to date) to limit the legal or regulatory options that are tabled. Science has undergone a paradigm shift in recent decades, and there is no reason to believe that law cannot undergo a similar shift. Certainly some legal values and principles will prove robust, indeed adamant, particularly at the abstract and macro level (as compared to the micro and individual action level), and autonomy is such a principle, but that should not overly restrict legal imaginariums. Other important principles concern the public interest, openness, access and sharing. It will be important to locate these values and principles within the pantheon of those implicated by the technological development under consideration, and also to query, as part of this process, approaches that have been relied on (successfully or unsuccessfully) in the past (such as criminal law approaches, the construction of authoritative architectures, the deferment to professional bodies, etc.). Again, such will enrich the process and open up possible options. A central unifying theme of the elements of this stratum is the possibility for – indeed, the need for – tolerance with respect to possible outcomes from the entire legal foresighting exercise. Having revealed value positions, attitudes and concerns about risks or other harms it will be important also to accept the need for trade-offs and compromises if progress is to be made. In short, the human condition and its politics must be allowed for.

The third stratum of this dimension of our matrix has to do with the subjects to be addressed in the regulatory foresighting exercise, the ultimate aim of which is to imagine and consider scenarios and weigh known and reasonably postulated factors, including existing and potential laws and regulations, so as to encourage a desired future. To that end, each foresighting exercise must delve deeply into three subjects –

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and S. Harmon, "Ambition and Ambivalence: Encouraging a Science Culture in Argentina Through Engagement and Regulatory Reform" (2011) 5 *Studies Ethics, Law & Tech* 1-26.

<sup>67</sup> A. Rip & R. Kemp, "Technological Change" in S. Rayner & L. Malone (eds.), *Human Choice and Climate Change*, vol. 2 (Columbus: Battelle Press, 1998) 327-399.

<sup>68</sup> In that regard, we draw attention to the manner in which legal – judicial and legislative – changes in attitude toward abortion (in a plethora of jurisdictions including Canada and the UK) lead to a more uniform social, or socio-moral, acceptance of the practice under certain conditions, and indeed generally.

<sup>69</sup> T. Swierstra et al. *supra*, note 64, at 121.

armed with the methods, understandings and foresighting tools delivered through our first two strata in this dimension.

As to subjects, first, and obviously, the exercise must consider ‘science’. A clear understanding of the local and international technical capabilities and trajectories, including funding tendencies and scientific objectives, as well as the known knowledge gaps and uncertainties, must be achieved. The second subject that must be exhaustively explored is that of ‘wellbeing’. As noted previously, health underwrites social functioning (and civilisation) and health generates wealth. Conceptions of, and demands for, health and healthcare must be understood, and must be capable of being placed in the broader global context. The third, and sometimes forgotten, subject that must be included is ‘commerce’. The proximity of both science and medicine to commerce must be appreciated; the development and success of the former two are now intimately tied with the latter, and all are entangled with the law.

The various domestic and international interfaces between these fields must be known. The law is the broad pallet on which these subjects are painted. The exercise must therefore employ investigations so as to arrive at understandings of the existing regulatory landscape *for each subject* (including the ethico-legal boundaries of conduct, how they are set, and how they are enforced). It must then consider whether and how (and how well) those regulatory systems communicate and work together. Only then can it claim to be adequately prepared to envision a future where all three issues might be substantially facilitated or supported by the law, and, more importantly, justly shaped and moved by the law (as each of the three should be). Imagining how conditions in the three subjects might be improved by the law should provide the basis for imagining how the law might be improved.<sup>70</sup> Supported ‘improvements’ may necessitate institutional or instrumental adjustment. We know from previous research that, in the sci-tech setting, enabling and discriminating policies are more likely to achieve aims and more efficiently than constraining and indiscriminate ones.<sup>71</sup> However, improvements may also call for radical regulatory realignment, something no serious legal foresighting exercise to date has been prepared to contemplate.

As should be clear, legal foresighting is about steering a path through innovation and precaution, social change and inertia, morality and the law, the latter which is naturally conservative, via a process that looks beyond the law, but that positions the law centrally so that the law might be moulded into more holistic and flexible forms, or, if needs be, radically re-imagined. Obviously, a plurality of opinions and positions can be expected, and therefore conflict can be expected. But plurality and its concomitant conflict need not be feared:

Diversity, heterogeneity, incommensurability, and antagonism – they can tear the fabric apart but they can also help to keep it vital and

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<sup>70</sup> Obviously, we are aware of the complex milieu into which the law is being injected and expected to act. Thus, and taking on board lessons learned, we therefore appreciate that most interventions at the legal level cannot claim linear or direct consequences, and will almost certainly result in unanticipated repercussions in other parts of the actor ‘system’. Having said that, one cannot deny that legal reforms can indeed have direct impacts on social or scientific practices, and therefore on technological innovations; the influence may not be linear and straight-forward, but it may certainly be real and measurable.

<sup>71</sup> J. Tait et al., *Policy Influences on Technology for Agriculture: Chemicals, Biotechnology and Seeds*, Final Report for PITA, Project No. SOE1/CT 97/1068 (2001), available at <http://www.technology.open.ac.uk/cts/pita/> [accessed 8 April 2009].

vigorous.<sup>72</sup>

In short, plurality and conflict represent an opportunity. Recall that the objective of legal foresighting is not to produce truth, but to stimulate social, moral, and, most importantly, legal imagination. The conclusions or results arrived at might be profound, both for the law as an institution and for groups and individuals as legal subjects and rights holders; negotiated courses of action may mean empowering new interests and weakening existing interests (and interest-holders) through the law. We expect that this might particularly be the case if the exercise signals a shift in socio-moral values, which is by no means beyond expectations.

For example, our empirical research in Argentina,<sup>73</sup> admittedly relying on a very small sample from which it may arguably be risky to extrapolate too broadly, suggests that there are some rather sharp divergences between three key elements in the Argentine techno-legal setting: the values the stakeholders expressed and what actions they felt those values demanded of them personally; the extent to which existing regulatory frameworks reflected those values and supported actions taken in response thereto; and the political possibilities having the former two constituents come together in a socially beneficial manner. The range of stakeholder meetings and interactions that we have conducted there suggests that a rather dramatic legal realignment would be welcome, as was recently achieved in Brazil in the stem cell setting,<sup>74</sup> and the Advisory Commission on Regenerative Medicine and Cellular Therapies (Advisory Commission), with the support of the Ministry of Science, Technology and Innovative Production (MOST), is aiming for such a shift via legislative reform.<sup>75</sup>

All told, this second dimension of the matrix, as with the first dimension, will have three strata each divided into three constituent parts (boxes). The first is defined by ‘participants’, ‘process’, and ‘method’, the second by ‘risk’, ‘values’, and ‘attitudes’, and the third by ‘science’, ‘wellbeing’, and ‘commerce’. See Figure 3

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<sup>72</sup> T. Swierstra & A. Rip, *supra*, note 34, at 19.

<sup>73</sup> The ESRC-funded GET: Social Values Project (see <http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/>) and the AHRC-funded ProReg Biotech Project and its related Biotechnology Consortium (see <http://www.law.ed.ac.uk/ahrc/research/viewprojects.aspx?id=13> and <http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/relatedprojects.asp>).

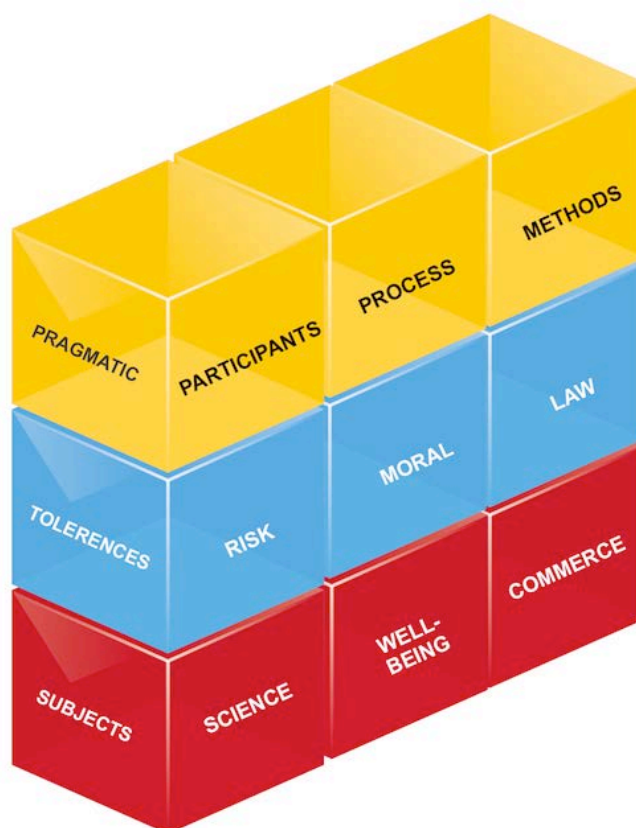
<sup>74</sup> See *infra*.

<sup>75</sup> These interactions include 22 qualitative stakeholder interviews as well as a series of 4 interactive stakeholder workshops held between 2007 and 2011 and involving as many as 40 key actors from a range of disciplines. For reports and recommendations emerging from these interactions, see S. Harmon, G. Laurie & F. Arzuaga, “Report: Regulation of Clinical Research Involving Stem Cells: Towards the Construction of a Regulatory Model for Argentina Learning from the Experiences of the United Kingdom” (2007), available at <http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/reports.asp>, S. Harmon & G. Laurie, “Opinion 4:2008: The Regulation of Human Tissue Use and Regenerative Medicine in Argentina: Making Experience Work” (2008), available at [http://www.mincyt.gov.ar/index.php?contenido=comision\\_celulas\\_madre](http://www.mincyt.gov.ar/index.php?contenido=comision_celulas_madre), S. Harmon, “Risk, Innovation, Diversity, Complexity: Policy Options and Objectives for Stem Cell Regulation” (2008), available at [http://www.mincyt.gov.ar/index.php?contenido=comision\\_celulas\\_madre](http://www.mincyt.gov.ar/index.php?contenido=comision_celulas_madre), S. Harmon, “Regenerative Medicine Governance: Report of the Workshop on Governance of Research Using Human Embryonic Tissue” (2009) 6:3 SCRIPTed 729-740, S. Harmon, “Opinion 4:2010: Guiding Values: Argentine Stem Cell Research and Regenerative Medicine” (2010), available at <http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/files/policybriefs/genomicstestone11singledocument.pdf>, and S. Harmon, “Opinion 5:2010: Health Research Governance: Argentine Stakeholder Objectives” (2010), available at <http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/files/policybriefs/genomicstestone12singledocument.pdf>.



below.

**Figure 3: Second Dimension**



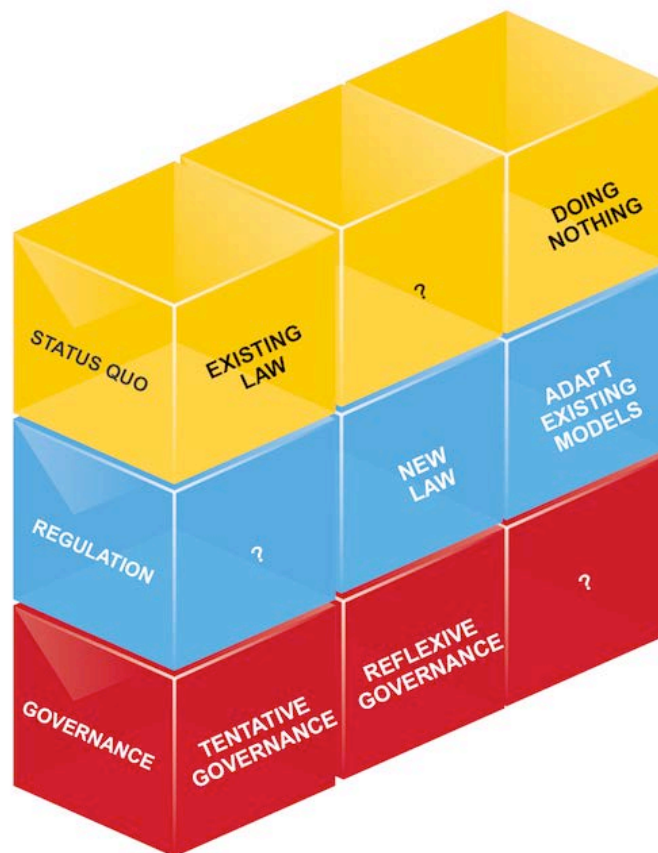
*3D Matrix -Third Dimension Considerations: Constructing Effective Legal Responses*

This brings us to the final dimension of our legal foresighting matrix: imagining how the law might respond. We suggest that, unlike the preceding dimensions of the matrix, this particular dimension must necessarily remain incomplete. The only limit to a foresighting exercise is our own imaginations as moulded by the particular findings of any given exercise with respect to any given new technology. It would be inappropriate and counterproductive to be prescriptive. However, there are *not* infinite ways in which law *can* respond. Indeed, important lessons can be learned from the deployment of law to date to assist our imaginings in a novel setting. Accordingly, we suggest that the three strata which make up this dimension should only be defined in broad terms. They are (1) status quo, (2) (novel) regulation, and (3) (novel) governance, and are illustrated in Figure 4.

With respect to the first of these, 'status quo', it is of course open to us to do nothing with the emergence of a new technology from a legal perspective. Such a course might be optimal where, for example, it is the case that existing legal provisions perfectly adequately accommodate the innovation, or where it might be untimely for the law to intervene lest it thwart a particular technology trajectory or divert it from its natural path. Whatever the reasons, doing nothing is always an option.

With respect to both ‘regulation’ and ‘governance’, we recall our earlier distinction: *regulation* will tend to be a state-driven, vertically-oriented, top-down, command & control deployment of legislation or other hard law means; in contrast, we conceive of *governance* as a far more horizontal-oriented enterprise, more likely driven by actors involved in technology development and adoption, and more reliant on soft law options such as guidance or professional best practice. These characterisations are not intended to be definitive nor should they be seen as prescriptive in how such legal devices might be constructed. They do no more than offer a template which can serve to focus our foresighting futures with respect to the entire armamentarium of law.

**Figure 4: Third Dimension**



**PART IV: LEGAL FORESIGHTING IN PRACTICE?**

As an illustration of how we see our matrix working in practice – and of how these broad parameters might be used to construct possible (and actual) futures – we offer three brief examples to conclude this article. As should be clear, legal foresighting, if it is to be done right and well, is no mean task, and it cannot be achieved in a stand-alone event. To be effective, the exercise must be programmatic; it will take time, preparation, multiple events, and funding support. But it can be done, and there are cases of sustained foresighting and engagement leading to radical legal re-imaginings. In other cases, we can identify instances where a legal foresighting matrix such as

ours could have improved legal developments. Brazil is one such example.

In March 2005, after years of engagement between researchers and patient groups and submissions from them to policy and governmental bodies, the Brazilian Congress passed (by a vote of 352-60) the *Biosafety Law*.<sup>76</sup> Article 5 of that law allows for the use of human embryos produced by IVF for research if certain conditions are met. In May 2005, the then Attorney General filed a Direct Unconstitutionality Claim,<sup>77</sup> alleging that the Constitution stipulates that life occurs at the moment of conception and Article 5 therefore contradicts the constitutional principle of the inviolability of life. In April 2007, the Brazilian Supreme Court held public hearings – for the first time in its history – during which it heard testimony from a range of experts. In May 2008, the 11-member Court ruled (by a vote of 6-5) that Article 5 is constitutional. Throughout this period (pre-2005 to 2008), stem cell research suffered some uncertainty in Brazil,<sup>78</sup> but by October 2008 the first Brazilian stem cell line had been announced.<sup>79</sup> Also during this period, Brazil experienced intense information exchange and debate:

The hearings at the Supreme Court demonstrated a democratic aspect of Brazilian society. Rarely has Brazilian society discussed any aspect of science or public health with such an intensity. Rarely have so many well-informed people expressed an opinion about a subject with legal, religious and scientific implications. Never before have Brazilian media realised such a wide coverage of science communication in a short period of time.<sup>80</sup>

While the Brazilian experience obviously does not reflect all of the elements of our matrix, it demonstrates that, even in jurisdictions where conservative socio-political institutions (like the Catholic Church) have significant political and social influence, there is scope to fundamentally alter the regulatory landscape and thereby redefine the scientific and social environment, even in morally-pregnant technological contexts. We can only speculate what might have happened had Brazil adopted a legal foresighting mechanism such as that offered in this article. It might, for example, have brought about the above changes more quickly and avoided the need for the Supreme Court itself to intervene in a public engagement exercise. While innovative, this raises serious constitutional questions about institutional legitimacy. This might mean, in due course, that the reforms themselves are questioned. This example effectively illustrates not only that assumptions need to be, and can be challenged, but also that there is a need to better capture legal imaginations and give effect to them in practice.

As an illustration of how our matrix might yet be deployed precisely in this regard, we offer the example of Argentina. Through the ESRC-funded GET: Social Values Project,<sup>81</sup> and the AHRC-funded ProReg Biotech Project,<sup>82</sup> we have generated

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<sup>76</sup> Law No. 11,105, 24 March 2005.

<sup>77</sup> Ação Directa de Inconstitucionalidade 3,510. The subsequent Attorney General filed a supporting brief with the Supreme Court.

<sup>78</sup> M. Leite, “Stem Cell Research in Brazil: A Difficult Launch” (2006) 124 Cell 1107-1109.

<sup>79</sup> D. Diniz & D. Avelino, “International Perspective on Embryonic Stem Cell Research” (2009) 43 Rev Saúde Pública 541-547.

<sup>80</sup> C. Jurberg et al., “Embryonic Stem Cell: A Climax in the Reign of the Brazilian Media” (2009) 18 Public Understanding of Science 719-729, at 727.

<sup>81</sup> See <http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/>.

<sup>82</sup> See <http://www.law.ed.ac.uk/ahrc/research/viewprojects.aspx?id=13> and <http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/relatedprojects.asp>.

a (small but sound) evidence base for the claim that stakeholders confronted with the socio-legal and cultural particularities of Argentina and its mature but modest regenerative medicine scene desire a top-down regulatory rather than a purely soft law regime. We have also uncovered a rich collection of values felt to be important to the science and its governance, including solidarity, knowledge, democracy, dignity, autonomy, honesty, transparency, and others.<sup>83</sup> Obviously, some of these values, which are not measurably different in definition from parallel values in other jurisdictions, may come into direct conflict (or demand contradictory actions of stakeholders). For example, relying on the values of autonomy and knowledge, participants felt that responsible scientists ought to be able to pursue their inquiries freely, even if the field in question was controversial. However, they simultaneously acknowledged that Argentina faced particular health and social dilemmas that must also shape those inquiries. Similarly, scientists expressed a desire for freedom to openly pursue and report on their research. But, again recalling the value of democracy, and human wellbeing or social benefit, they acknowledged a (currently unmet) need and personal desire to engage with wider publics to better understand their values, social objectives, and health needs.

In any event, exploring this conflict with relevant stakeholders through the matrix offered above will not only enlighten Argentine stakeholders (important in itself), but will also help them to uncover potential regulatory responses to the science in question (regenerative medicine) and its concomitant technologies and practices. While we have begun the necessary discursive process, and in doing so have introduced an element of reflexivity insofar as we have generated ‘learning’ from the successes and failures of the UK experience, the legal foresighting exercise remains incomplete. But crucial elements of the matrix have begun to be filled in. We have, for example, identified and systematically engaged with key stakeholders including the Argentinean government, the research community, lawyers and law-makers, ethicists and patient groups. We have uncovered the complex set of values in play and attitudes towards a role for law. Perhaps surprisingly, the view which is emerging is one more in favour of a top-down regulatory approach, both for the protection this brings to research participants and to researchers alike, and for the belief that it is the optimal way to secure confidence in the quality and international marketability of Argentinean research. Next steps include wider engagement (e.g with religious communities) and further testing of the possible legal models that might be adopted. A conclusion from work to date is that what is required for Argentina in the context of stem cell research is a federal law to regulate the field and the translation of research into therapeutic applications. We are working with the MOST, other relevant regulatory bodies such as INCUCAI,<sup>84</sup> and the national Congress in this regard.<sup>85</sup>

Finally, we offer a contrasting example which does not come from the developing world and which does not involve recourse to hard law; it is useful because it typifies the notions of ‘governance’ we offer above. This example draws on the experiences of one of us (Laurie) who has been involved in the process of governance design in the field of biobanks.<sup>86</sup>

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<sup>83</sup> For a further extrapolation of these values, see S. Harmon, “Opinion 4:2010: Guiding Values: Argentine Stem Cell Research and Regenerative Medicine” (2010), available at <http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/files/policybriefs/genomicstone11singledocument.pdf>.

<sup>84</sup> The national transplantation authority under the Ministry of Health.

<sup>85</sup> See [http://www.mincyt.gov.ar/ministerio/estructura/unid\\_asesoras/com\\_atcymr/vision.php](http://www.mincyt.gov.ar/ministerio/estructura/unid_asesoras/com_atcymr/vision.php).

<sup>86</sup> Obviously, nothing said herein should be taken to reflect the views of any parties other than the authors of this paper.

UK Biobank is one of the world's largest biobanking projects, containing data and samples from over 500,000 adults collected when participants were between 40 and 69 years of age. The overarching objective of UK Biobank is to create a research resource that will be accessed from all over the world to promote the broad objective of 'health-related research'. The value and richness of the biobank derives not only from its extensive baseline collection but also from the fact that participants have agreed to be followed throughout their lives via their medical and other health-related records, and to be re-contacted if necessary for further samples or investigation. In ethical, legal and regulatory terms, UK Biobank represents numerous challenges. A plethora of questions arise about the nature and validity of participants' consent, the security of their data, the basis upon which the resource will be accessed now and into the future, property in and control of the resource, and, ultimately, protection of participants' interests when the explicit aim of the project is to promote wide access and to exploit the resource in the public interest.<sup>87</sup>

These issues have vexed the funders since the inception of UK Biobank. One might think that the project is ripe for legislative regulation and oversight, yet no specific law has been passed in this respect.<sup>88</sup> Instead, UK Biobank has embarked on a grand governance experiment. It is a paradigm example of bespoke governance arrangements that have been shaped by the ever-changing scientific protocol itself and in tandem with such developments. The UK Biobank approach invokes soft law options that are designed to reflect and respond to the particularities of the initiative. Two aspects are worthy of note: (1) its Ethics and Governance Framework (EGF) and (2) its Ethics and Governance Council (EGC). The EGF is a public instrument from UK Biobank that makes explicit the core undertakings of UK Biobank to its participants, researchers, and wider society. It is a living document which is designed to adapt as science, society, and the project progresses and faces unforeseen challenges. The EGC is an independent oversight body charged with the responsibility to monitor and advise UK Biobank throughout the life of the project, most particularly with respect to its conformance with the EGF and protection of the interests of participants.<sup>89</sup> The EGC acts as a 'critical friend' to UK Biobank as it faces the uncertainties that arise from its longevity and wide-ranging objectives.

We have argued elsewhere that this experiment in governance is, in fact, an example of *reflexive* governance.<sup>90</sup> We conceive of reflexive governance as one possible outcome of a legal foresighting exercise. In its specifics, it is about in-parallel partnership in governance in the face of future uncertainty.<sup>91</sup> It is about the facilitation of mutual learning from experience over time. It can be seen as "...a mode of steering that encourages actors to scrutinise and reconsider their underlying

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<sup>87</sup> These matters are discussed, inter alia, in J. Kaye and M. Stranger (eds.), *Principles and Practice in Biobank Governance* (Farnham: Ashgate Publishing, 2009); K. Dierickx and P. Borry (eds.), *New Challenges for Biobanks: Ethics, Law and Governance*, (Antwerp: Intersentia, 2009); H. Widdows and C. Mullen (eds.), *The Governance of Genetic Information*, (Cambridge: Cambridge University Press, 2009); M. Hayry, R. Chadwick, V. Arnason and G. Arnason (eds.), *The Ethics and Governance of Human Genetic Databases*, (Cambridge: Cambridge University Press, 2007)

<sup>88</sup> UK Biobank is subject to a plethora of existing legal provisions protecting participants' interests and has not required any legislative intervention in this regard: G. Laurie et al., *supra*, note 44.

<sup>89</sup> Laurie was Chair of the UK Biobank Ethics and Governance Council from September 2006-December 2010. Nothing said in this article should be taken to reflect the views of the EGC or any individual or organisation associated with UK Biobank.

<sup>90</sup> G. Laurie, "Reflexive Governance in Biobanking: On the Value of Policy Led Approaches and the Need to Recognise the Limits of Law" (2011) 130 *Human Genetics* 347-356.

<sup>91</sup> B. Wynne, *supra*, note 10.

assumptions, institutional arrangements and practices.”<sup>92</sup> According to Vincent-Jones and Mullen, “[t]he legal framework by itself is incapable of facilitating the conditions necessary to promote a sufficiently receptive and deliberative orientation on the part of the relevant actors.”<sup>93</sup> Rather, “...fully reflexive governance is dependent on deliberation and openness to alternative possibilities in the framing of problems and the suggestion of solutions...”<sup>94</sup>

The UK Biobank example, seen in this light, is a possible model that can inform future foresighting exercises. It is neither a version of top-down regulation nor a system of up-front ethical approval of a scientific protocol, each of which might be too limiting and incapable of accommodating the uncertainties which biobanks and many new technologies generate. Reflexive governance provides a system of organic co-production of responses which, as we have suggested, are central to optimal legal and regulatory foresighting. Moreover, such an approach is both responsive to the demands of the particular initiative or technology and, at the same time, able to take in account a range of values and interests which can — and will — change over time.<sup>95</sup>

While these three examples do not demonstrate full-blooded examples of the legal foresighting matrix as elaborated above, we believe that they rather help to illustrate the range of possible imaginings that can be facilitated by our matrix. The core value of our model is not to point to any given legal response to any particular new technology, nor to privilege one particular response (regulation or governance) over any other. Rather, it is to provide a robust framework for identifying and considering the range of key issues and possibilities that must be taken into account if law and science are to work better together to produce a better and more just society.

## CONCLUSION

Foresighting is not about taking the pulse of diverse stakeholders. It is not simple opinion surveying or mere public participation, nor is it post-hoc legitimation. Foresighting exercises, particularly legal foresighting exercises, must be keenly aware of the following ultimate objectives:

- the discovery of shared values;
- the development of shared lexicons;
- the forging of a vision of the future; and
- the taking of steps to realise that vision with the understanding that this is being done from a position of partial knowledge about the present.

Legal foresighting demands the deployment of a variety of methods to obtain evidence from a variety of stakeholders with a view to achieving a particular end, that end being the better understanding of possibilities and issues around a subject with a

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<sup>92</sup> C. Hendriks and J. Grin, “Contextualising reflexive governance: the politics of Dutch transitions to sustainability” (2007) 9(3) *J of Envir Policy Planning* 333-350.

<sup>93</sup> A. Rip & R. Kemp, “Technological Change” in S. Rayner & L. Malone (eds.), *Human Choice and Climate Change*, vol. 2 (Columbus: Battelle Press, 1998) 327-399. P. Vincent-Jones & C. Mullen “From Collaborative to Genetic Governance: The Example of Healthcare Services in England” in O. de Schutter & J. Lenoble J (eds.), *Reflexive Governance: Redefining the Public Interest in a Pluralistic World* (Oxford: Hart Publishing) 147-178, at 153.

<sup>94</sup> *Ibid*, at 175.

<sup>95</sup> For further exploration of the nature and value of reflexive governance in the biobank context see G. Laurie, *supra*, note 31.

view to marshalling resources and expertise to achieve a shared vision of the future. More specifically, it is about determining how the law can be deployed to bring about that future.

In this effort, regulators ought to be ‘first movers’, and they ought to be concerned with ultimately fashioning ‘smart regulation’ (ie: imaginative, flexible, user-friendly, holistic, and joined-up regulation).<sup>96</sup> It is important to recall that complex settings do not necessarily require complex legal frameworks. In fact, overly cluttered and fragmented frameworks, from institutional and instrument perspectives, can be profoundly counter-productive to promoting (1) socially-sensitive innovation, (2) effective risk assessment, tracking and management, and (3) timely delivery of socially beneficial outputs. This requires value clarity, objective clarity, duty-clarity, and oversight, whatever the substantive content and mechanisms of the system. The legal foresighting matrix offered herein provides an effective, systematic, pragmatic and flexible mechanism to foresighting futures by placing the role of law at the heart of the exercise.

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<sup>96</sup> By ‘joined-up’ we mean that the regulatory regime should be approached with a view to enhancing communication and partnering across regimes (eg: as between basic research and clinical regimes, healthcare and property regimes, etc.). Previous research has found that inconsistencies and antagonisms among policies grounded in different policy arenas and government departments hinder the realisation of social aims: J. Tait et al., *supra*, note 71. Emerging evidence suggests that regulatory rigidity and complexity increases costs and uncertainty, both industry and social, and serves as barriers to efficient governance and effective innovation. As such, conflicting demands and standards should be eliminated or minimised, and the formation of channels of authority and responsibility must be clear, not overly complex, and joined up or shared across sectors.