PART II

Regulatory Immunity

In Part I, I concluded that neither global hegemony approaches nor approaches that emphasise the scientific rationale of regulation can satisfactorily explain the global dynamics of regulatory development in the field of regenerative medicine. In Part II, I show that the desire to compete leads governments to develop a form of regulatory capacity building that requires both following 'good' regulatory models and a moral defence of a country's regulatory reputation. It will become clear that a distinction between public and private regulatory interests (Chapter 1) in regulation are not very helpful when exploring national reputation, as the international politics of national and regional regulation conditions both. I will conceptualise these reputational factors by developing the notions of 'regulatory immunity' and 'immune tolerance' to clarify the global dimension of regulatory boundary-work in nation-state political strategies, in scientific collaborations and in scientific discourses and practices.

Regulatory Immunity and Reputation

Regulatory boundary-work is rooted in the politics of reputation. Reputation is *ascribed* by others and refers to the fulfilment of regulatory requirements, such as 'data transparency', 'scientific reliability', 'budgetary responsibility' and 'scientific excellence'. I use the notion of 'regulatory immunity' when a jurisdiction is thought to protect patients and high-quality scientific research mainly on the basis of reputation rather than evidence. Regulatory immunity, I argue, protects players against accusations of patient exploitation and scientific fabrication. And, as explained below, it points to dilemmas inherent to global regulatory harmonisation.

Importantly, regulatory immunity as an ascribed reputation is based on historical, economic and scientific bias, and it plays a crucial role in the politics of scientific and clinical development. The status of regulatory

immunity enjoyed by some jurisdictions, I argue, is subject to envy. Countries with regulatory immunity attract scientific collaborations and aspire confidence in the quality of their scientific research. For this reason, they can afford to engage in the most advanced experimental projects under exemptions or acceleration schemes without immediately rousing suspicions of gratuitous risk-taking or patient exploitation. 'Regulatory immunity' also allows a country a measure of tolerance for clinical practices that it would decry when conducted by 'Others'. It is the historically rooted nature of regulatory immunity that frustrates the desires of competing powers, such as the PRC and India, where many scientists lament the lack of recognition (Zhang and Datta 2022).

The concept of immunity, as discussed below, originates in a judicial metaphor, and it implies what we today associate with the meaning of 'diplomatic immunity'. Not until the nineteenth century was the notion of immunity associated with biology. In 1881, biologist Elie Metchnikoff explained the mobile cells gathered around a splinter in starfish larva as self-defence (Cohen 2009). The biological conceptualisation of immunity developed in parallel with social discourses in terms of defence and invasion. Thus, today, we still speak of the use of vaccination and antibiotics as a defence against the invasion of microbial enemies. I adopt these metaphors in my discussion of regulatory violence, as they presume a structural interconnectedness of conceptual paradigms based on warfare and can help explain political strategies of regulatory boundary-work.

The metaphoric parallel between the life-sciences and society has not escaped the notice of social science scholars, who have observed that, in the twentieth century, the immune system is often described in economic and military terms. Anthropologist Emily Martin showed how scientific descriptions of the immune system were the capitalist projections of Western societies as 'boundary-oriented, mutually interacting systems of hierarchically organized components' (Martin 1990: 415–416). She observed how the immune system in scientific descriptions illustrates how economic and military metaphors of the immune system portray relations between the national Self and Other (Non-Self) countries. Similarly, anthropologist Donna Haraway explored immunologist Niels Jerne's notion of immunity as a world of 'internal imaging' demonstrating that 'there is no external antigenic structure that the immune system has not already "seen" and mirrored internally'

(Haraway 2013: 291). Projected back onto the world of global capitalism, the notion reflects the hostile adaptive reactions of nation-states to perceived outside threat.

In the context of global research governance, the metaphors of 'mutually interacting system of hierarchically organized components' and 'internal mirrorings' characterise the globally interconnected regulatory relations among and within nation-states, embodying a dynamic hierarchy descending from well-regulated, kosher elite laboratories to evasive, rogue clinics. Relevant to my discussion on regulatory immunity and tolerance is how 'immunised' regulatory Selves *internalise* the decried activities of invading Non-Selves, rather than *rejecting* them.

Below, I will elaborate on three different aspects of 'immunity' central to my discussion of regulatory violence and regulatory brokerage in the field of regenerative medicine: First, its inoculatory effect on a science community regarding the violation of regulation and the exploitation of patients (regulatory immunity); second, the legal tolerance for players with a privileged status (regulatory immune-tolerance); and, third, the absence. of credible regulatory authorities in global regulatory capitalism, that is, a regulatory immune vacuum. The three aspects will be exemplified in the next chapters.

Regulatory Immunity

The first aspect of immunity as used here refers to protection from violation in an environment of competition. French anthropologist René Girard explains the establishment of law as a form of immunisation against violence associated with envy and competition (Girard 1986, 2020). Girard roots competition in what he refers to as mimetic rivalry, a form of competition based on self-identification with others. Rivalry leads us to want what others have, turning competitors into models for and objects of desire. Ultimately, Girard argues, reciprocal or imitative desire, unconstrained, will spiral into potentially all-destructive violence. Analysing ancient mythology, Girard shows how 'immunity' initially emerged when escalating violence through spirals of revenge was halted by the offering of a human or other kind of scapegoat. Over time, however, immunity against violence through scapegoats made way for a new form of 'immunitas', which emerged

with the establishment of 'the law'. This communal law avoided escalating violence by the application of immunitarian force through an exteriorised body: the judicial system (Girard 2020 [1977]).

In democracies, potential violence is invested in the judicial apparatus, backed up by police and military force. Here, immunitas is based on the fundamental ambiguity that the community is held together not through social affiliation but by the threat of judicially authorised external force. Similarly, external regulation in regenerative medicine is a permanent reminder that spontaneous self-regulation by the science community is not recognised. The regulatory appropriation of the power to assess and adjudicate scientific practices through penalties or permissions becomes a transcendental, immunitary force. Its powers of authorisation, and pre- and proscription are crucial to those who depend on the regulatory authorities for operating stem cell–related activities. Thus, regulation affects how scientists operate, their access to funding and their reputation for scientific rigor and quality. The notion of regulation in regenerative medicine as inocculatory limits the possible activities of researcher-clinicians, who, without constraint, could do obvious harm in a world of competitive capitalism. The mimetic rivalry in the race for clinical firsts threatens to spiral into harmful interventions, so that without regulation, clinical research would not only fail to adhere to scientific research but also form a threat to potential patients. Due to the immunitarian transfer of power to the state, instead of the researcher-clinician, the regulatory authorities now have the power to do harm, but they also have the capacity to facilitate the 'acceptable' development of scientific applications. Of course, the question of what is acceptable (safe, efficacious, ethical applications) science remains contested and has both national and global dimensions.

Regulatory Immune Tolerance

This second aspect of immunity I use to draw attention to the privileged positions occupied by the immune due to their special status. Regulation provides rules to enable clinical trials. Those that follow the regulations receive permission that make researchers (relatively) immune to penalisation; without regulation, their research would be considered experimentation. In regenerative medicine, regulation can also make exemptions creating an immune enclavement within the

immunity of regulated research. This notion of immunity was first used in Roman law over two thousand years ago (Girard 1986, 2014; Cohen 2009; Esposito 2011) to refer to 'immune' service-providers and functionaries from abroad. The immune aliens were given Roman citizenship with privileges and entitlements, such as exemptions from paying taxes and from legal culpability. This arrangement raised a worrying matter: how could it be that a universal Roman Law was applied to all citizens, but not to some? It implied that it was not social belonging, but the law that determined one's identity. The liminal position of these 'immune' citizens rendered them suspect (Cohen 2009: 40–42; Esposito 2011). Philosopher Roberto Esposito explains how, evolved as a protection from the obligation to reciprocate, 'immunitas' points to a parasitical relation with the community (Esposito 2011: 22–28). In Part II, I develop the notion of immune-tolerance to refer to the tolerance a community reserves for the privileged position of members of the community who are not expected to be subject to the same duties, laws and values.

Such immune-tolerance is relevant to my exploration of the dynamics of regulatory regimes in the field of regenerative medicine. In the grey area between 'rogue' and 'kosher', stem cell interventions (SCIs) (Chapter 2), clinical researchers and providers who violate state regulations are in a similar liminal position. Thought of as bending or violating the regulatory standards and values of the established community of regenerative medicine, they may be accused of exploiting patients and reproached for parasitical behaviour. What makes this category as ambivalent as the foreign service-providers and functionaries mentioned above is that, although violating state regulations designed to guarantee patient safety and science quality, they nevertheless have the freedom to go on to provide their services. They may be ignored or perhaps warned, but, in the end, they are able to continue their clandestine activities. Therefore, although national authorities can deal with conflicts about the meaning of safe, efficacious, ethical applications through regulation, thereby immunising the science community against ethical and scientific violations, it also tolerates violations; and although regulatory authorities can control mimetic rivalry in principle, regulatory authorities also tolerate prohibited practices and practices that the spirit of the regulation does not support. The notion of immune tolerance, then, stands for the active maintenance of de facto tolerance for regulatory offenders, indirectly

denying everything that the spirit of the state stands for. Chapter 4 details examples.

The Regulatory Immune-Vacuum

This third aspect of the notion of immunitas draws attention to the symbolic message that a community's regulatory regime communicates to outsiders, and which ultimately forces us to recognise that the globalised world of today exists in a regulatory immune-vacuum. To arrive at this conclusion, one needs to trace the role of transcendental power in the process of globalisation. On the one hand, regulatory immunity is about the protective and enabling *transcendental power* of the law or regulation, which is directed towards protecting the community of regenerative medicine against violations of particular collective standards and values and to the enablement of stem cell scientists to conduct innovative/experimental research under the protection of the law; on the other hand, regulatory immunity refers to the *discursive message* directed against undesirable ways of regulating regenerative medicine. Such messaging is of crucial importance to the identity and reputation of a domestic science community. However, some experimental activities that are proscribed 'at home' can nevertheless be of substantial value to a country. It is here that the notion of mimetic rivalry at a national level can explain why a country, even though it may violate its own regulation, or its regulatory spirit, might decide to 'tolerate' unauthorised experimental practices. But this raises the question of how regulatory integrity is maintained if practices for which foreign governments have been scapegoated are allowed in home territory. To explain this, we have no choice but to use the perspective of globalised regulatory capitalism.

According to Girardian anthropologist Mark Anspach, in absence of a global state, despite the existence of global institutions, the international arena of capitalism resembles the condition of a pre-law society: today no global authority exists that can occupy the position of the 'commune', which means that violence cannot be exteriorised by some transcendental authority. Consequently, global capitalism lacks solid communal norms and values. Whilst cultural traditions of giving underlie the sustainability of societies based on solidarity and gift exchange, exchanges based on 'market transaction' do not have the ability to go beyond the stipulations of the contract. In this sense, market exchange does not compel an adherence to ethical obligations, allowing cheating, stealing and warfare

(Blanc and Bessière 2001). The question I am interested in here, and which will be discussed in Chapters 4 and 5 and Part IV, is this: How, in a world connected through regulatory capitalism, is how regenerative medicine to be adjudicated without the external authority so crucial to the nation-state's condition of immunitas? In other words, given the global regulatory immune-vacuum in a world dominated by regulatory capitalism, how do states regulate to protect patient health and science quality where imitative desire cannot be sufficiently tempered? In the context of regenerative medicine, I will speak of 'competitive desire' to capture what Girard refers to as 'mimetic rivalry' and 'imitative desire'.

The two chapters that follow illustrate the role of regulatory immunity in the international regulation of regenerative medicine. In Chapter 4, I explore the real-world consequences of the discursive identification of regulation with 'kosher' or 'rogue' science and how the kosher science of the national Self is foiled against that of rogue competitors. Asking how frictions between Self and Non-Self are tolerated in terms of regulatory immunity, I will use a range of examples in the field of so-called adult stem cell applications to illustrate the meanings and effects of scientific boundary-making and regulatory scapegoating in what I refer to as conditions of 'immune tolerance'.

The point of departure in Chapter 5 is the global 'immune-vacuum': the absence of a credible international regulatory authority for regenerative medicine. Although there exist global institutions that issue informal guidelines, such as the ISSCR, the guidelines are contested: highly respected by elite research institutions and opposed by alternative organisations that prefer 'real world' regulations, such as International Cellular Medicine Society (ICMS), SCI-Net and the International Association of Neurorestoratology (IANR) discussed in Chapter 2. In other words, there is no transcendental institution that can immunise the world against the spiralling effects of competition, leaving translational medicine insufficiently protected against unconstrained bureaucratisation, where elite standards are currency, and against escalating regulatory inflation as a result of pressures from industry and health activists. I will explore both sides of this authority vacuum by investigating how regulatory discrepancies are negotiated between countries. Using the notion of regulatory capital, I ask how regulatory integrity is maintained in a case study of international science collaboration around a stem cell processing robot installed in Bangkok based on regulatory capital, afforded by perceived regulatory lenience.

In short, in Part II, I use the notion or regulatory immunity to shed light on key internal contradictions in the regulation of regenerative medicine and to draw attention to what remains unexpressed and unacknowledged by national authorities in the logic of regulatory immunity. The resultant renewed focus will encourage us to assume a wider, global perspective on ethics, justice, fairness and life itself and reflect on whether global transcendental immunity is either feasible or desirable.