cell lines that scientists may need. Existing banks and repositories also suffer unnecessary overlap and duplication of effort and lack interoperability, limiting their utility to scientists (3, 5, 6).

For example, a recently issued statement by the Hinxton Group (7) notes that problems with access are twofold, involving access both to cell lines themselves and to critical information about those lines, including technical, provenance, and IPRs characteristics. They note, “…many cell lines are being derived and characterized, though not all lines are being published in the literature, even in the academic sector. Furthermore, useful cell lines created from human materials (especially those created with public funds) and their associated data should be distributed and used widely, constrained only by the wishes of the materials’ donors” (7). In addition, the statement observes that we currently have “a situation in which even a diligent stem cell researcher or entity that wishes to respect IPRs will face considerable uncertainty and enormous costs if they try to survey the IPRs landscape” (7). To address these concerns, the Hinxton Group recommended developing publicly available electronic hubs for accessing a range of relevant data linked to individual stem cell lines. The vision is to coordinate extractable and linked identifying information is retained separately from the material to prevent any future permission (10).

Researchers currently protect confidentiality of donors’ data by one of two methods: anonymization, where identity is irreversibly severed from the material to prevent any future re-identification; or de-identification, where coded and linked identifying information is retained separately from the material. As the paradigm of single-center cell banking is increasingly replaced by multisite arrangements involving institutions across many jurisdictions, there are concerns that these confidentiality practices may be insufficient (5), and that the melding of persons and artifacts may lead to unprecedented violations of privacy and consent (11).
Private Property Versus Public Domain

Following trends seen elsewhere in the sciences, stem cell researchers—and the companies or universities for which they work—are increasingly taking private ownership of early-stage technologies, including cell lines, genes, and associated data (Fig. 2). Simultaneously, researchers in the field draw upon a common repository of knowledge and technologies considered to be in the public domain. However, the boundary demarcating what is public from what is private has become fluid and ill defined.

In theory, that which is in the public domain is defined by the absence of private legal claims of ownership and control. Thus, to the extent that private property is not clearly demarcated, the public domain is left ill defined. In stem cell science, the landscape of IPRs is complex, and its boundaries fuzzy. IPRs are not uniformly recognized, registered, or enforced globally: A technology may be closely held by a private owner in one country and effectively left in the public domain in others. Different, inseparable aspects of a technology may be subject to separate property claims; for example, patents could cover both the process to create pluripotent cells and the reagents necessary to do so. Moreover, multiple, narrow claims over interdependent aspects (or uses) of given technologies can create dense thickets of ownership claims that are costly to negotiate and transact.

This can be particularly problematic when information and materials are inseparable, as for a given technology, they and their uses may be protected separately—even by different types of property right. Materials may be owned as physical property. Methods of derivation or propagation may be patented. Associated information may simply be held as confidential or maintained in a private database.

The complexity of IPRs claims can also be compounded by the person-artifact dualism that characterizes human cell lines. For, in addition to any third-party IPRs claims over a cell line, methods associated with its derivation, or uses of it as an artifact, the donor may have legitimate personal property claims over the cells or their use, as well as privacy rights over associated information.

Full information and well-defined property rights are necessary conditions for markets to function efficiently. Without these conditions met in the market for stem cell technologies, search costs, transaction costs, and risk are imposed and detractions from the incentives that IPRs are intended to provide. What is needed is as reliable information as possible on where stem cell–related IPRs have and have not been claimed, held valid, and remain in force. This will, moreover, enhance the reliability of the public domain.

A Promising Start

The proposed information and materials hubs for stem cell research (7) may be a solution. Such hubs could improve access to data and materials generally and serve a gate-keeping function for access to various stakeholders, being mindful of ethics and IPRs concerns and providing a solution for mediating the complex and blurred distinctions described above.

The construction of such a resource could begin with developing a centralized datacenter for access to existing resources, one that aggregates key data characterizing their available materials. Additional features, such as IPRs information, and provenance and consent characteristics, could be added as funding becomes available to support the necessary programming and database research. The integration of these kinds of information would produce the greatest value-added to the community (12). Critical to the success of such a resource are commitments from the members of the scientific community to contribute to and curate the information in the resource, and from funding agencies to support the work.

There are substantial challenges in developing such a hub, however, including who will fund it, who will do the work, what the resource will look like, where it will reside administratively, and how the various blurred distinctions will be facilitated and managed in practice. We need to think critically about the design of data architectures to provide gate-keeping functions for access by various stakeholders, such as where restrictions on use or existing IPRs require formal negotiations and legal agreements. Expertise needs to be developed across these domains, with fresh thinking about the dualisms and how to manage them. Further research may be needed to learn how potential donors view their tissues, their relationship to those tissues following donation, and their own rights relative to third-party IPRs claims over those tissues.

These issues are increasingly prevalent across biomedical science, including biobanking, genetics and genomics, and personalized medicine. Community resources of this sort are emerging as necessary infrastructure of the scientific enterprise, no longer an aberration or exception to the rule, but rather the way research communities must function to move forward.

Fig. 2. Stem cell patents and patent applications published by various patent offices. Data source: Thomson Innovation (2010), queried using methods of Bergman and Graff (13).

References


10.1126/science.1201382