

# University-Industry Relations & Some Lessons from Biotech

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Increasing university-industry interactions may be seen as raising no real concerns, or even as being an unqualified good. Benefits of this interaction include increased funding for science and the conversion of esoteric knowledge into real-world products. But this interaction is not without controversy. There are growing concerns about academic freedom and integrity, conflict of interest, and whether good science will be jeopardised by pressures to become product oriented. These issues will be examined by exploring the case of genomics and biotechnology, an outstanding example of science being pushed and pulled into the commercial sector by a host of public and private forces. The closing decades 20<sup>th</sup> century may have been the age of computers and information technology, but the 21<sup>st</sup> century will be the age of biotechnology. The sciences of genetics, genomics and biotechnology are seen to hold the answers to many of the world's major problems. Genetically modified foods will feed the developing world and deliver cheap medicines (despite the fact that hunger is largely the result of poverty); genetically engineered organisms will heal the environment (a technical solution to an industrial problem?); and gene therapies and biopharmaceuticals will cure cancer and eliminate diseases (although this may have little effect on population health issues).

While the potential health benefits to be derived from biotechnology are clearly an important motivator of the substantial public interest and investment we've seen to date, another major driver is the conviction (especially on the part of governments and financial markets) that biotechnology is essential for economic growth and building a 'knowledge-based economy'. Thus unlike many other basic or applied sciences, enormous amounts of public and private funds are being invested in genetics research and biotechnology development [1]. The total

US public expenditure on the Human Genome Project is estimated at greater than \$3 billion US, while the US biotechnology industry invested \$15.6 billion US in R&D in 2001 alone. In Canada, annual federal science and technology expenditures on biotechnology reached \$314 million in 1998, of which \$310 million was devoted to R&D; these expenditures have continued to grow, and with the creation of Genome Canada in February 2000, the federal government expanded its support with a one time investment of \$300 million for genomics R&D. Between 1989 and 1995, annual expenditures on biotechnology R&D by Canadian industries grew from \$116 million to \$341 million [2]. Similar public and private funding initiatives are occurring in the U.K., Europe and Asia.

The last few decades have seen increasingly close interactions between academic and commercial entities. Private financing has gone into the funding of major genetic and genomic projects and research centres, graduate students are receiving training in commercial laboratories, and academic scientists are 'spinning-off' their work into start-up companies or patents that may be commercialised or licensed. With the blessing of universities, scientists are now engaged not only in the production of knowledge but in the transfer of technology. This shift in focus has resulted in part from changes in government perceptions of the function of academic institutions. Universities are no longer seen primarily as centres for the generation of knowledge - they are now considered drivers of technology development and economic growth.

There has been pressure from provincial and federal governments, the federal granting councils, and university administrations to focus funding on applied research, increasingly to the detriment of more basic research. University and government programs have been developed to build linkages between university researchers and industry partners. Financial investments

in biotechnology have also been supported by government policy and regulation that facilitated technology transfer and commercialization [3]. International intellectual property law (driven by US legal decisions and international trade and patent agreements) has made possible the patenting of biological materials and the granting of thousands of gene patents. Governments in the US, Canada and Europe have enacted legislation (e.g., the 'Bayh-Dole Act' in the US) to encourage publicly funded researchers to commercialize their work (where previously public funding had barred commercialization) in the form of patents, licenses and spin-off companies. Universities have responded to this increased freedom by creating technology transfer and industry liaison offices, and according to one US study, by 1995 more than 40 per cent of all gene patents were held by public institutions or charities [4].

This regulatory climate helped create a positive environment for commercial development, and small and medium sized biotechnology start-up companies (whose primary assets were often patents on potential 'disease genes') proliferated in the US in the early 1990s. Annual revenues from the US biotechnology industry more than tripled between 1993 and 2001, to \$27.6 billion US; this industry is also estimated to have created (directly and indirectly) 437,400 US jobs, generated \$47 billion US in revenues, and provided \$10 billion US in taxes for federal, state and local governments. In Canada, there are more than 500 biotechnology companies with industrial activities generating combined annual revenues of \$2 billion and exports of more than \$750 million. Despite the apparent economic success of this industry, there has also been a high turnover of biotechnology companies, with only a small percentage remaining solvent a few years after start-up, and even fewer able to show a profit - between 1992 and 2002, the number of

US companies only grew from 1,231 to 1,457, with many start-ups being swallowed by established biopharmaceutical companies. And with increasing interest by developed and developing countries in reaping the economic benefits of biotechnology, there is also growing competition to attract companies away from neighbouring countries. The direct national economic benefits of investment in biotechnology infrastructure may be diminishing as the industry becomes more international and concentrated within fewer multi-national corporations.

Beyond the strict economic concerns, the change in funding of research and pressure to commercialize has led to changes in the conduct of academic science. While proponents of patenting of academic research argue that such protection is essential both to support new and speculative work as well as to promote effective commercialization and dissemination of the products of research, patents may also hamper research due to increased secrecy and multiple overlapping patent claims that make some research too costly to pursue [5]. Patents are one of the most often cited reasons (along with internal academic restrictions and issues of crediting and authorship) for restrictions or delays in scientific publication. Requirements such as non-disclosure agreements may be initiated by or placed on scientists that inhibit academic debate and publication. Researchers may themselves have financial interests in products of research, such as owning shares in companies that commercialize their research, or be in a conflict of interest in publishing research results supported by commercial sources [6]. All of these interests have the potential to seriously retard timely publication and threaten the objectivity and credibility of the scientific process [7].

Even without the influence of patents, the commercial nature of biotechnology research can lead to reduced collaboration and increased secrecy. A focus on trade secrecy as a means of protecting products or inventions may make researchers and companies less likely to share research discoveries [8]. While patents may mitigate these effects by requiring public descriptions of the patented product, when combined with other commercial incentives, patents may contribute to an increasing culture of secrecy. Scientific progress is usually seen as the result of a division of intellectual labour and the dissemination of results in academic and public forums, thus a climate of secrecy has serious

negative implications for the conduct of science in the university setting. Further, some areas of investigation may be insufficiently product focused or likely to result in a marketable discovery, and thus be deemed 'un-fundable'. And given the rapid turnover of biotechnology companies, scientists may lose all control over their discoveries when the companies they have established collapse due to insufficient venture capital, or are taken over by large biopharmaceutical companies.

The case of biotechnology provides some important lessons. Many scientists will increasingly face a host of complex social and ethical issues. Some of these can be dealt with by pushing university and government representatives for more effective regulation to address issues of conflict of interest and academic freedom. There must be mechanisms to protect scientists, their students, and research subjects from the negative effects of powerful commercial influences that may undermine the conduct of safe and rigorous science [9]. Scientists as individuals and through their professional associations must continue to push for the highest standards of transparency and peer-review in research publication, if they are to continue to be seen by the public as worthy of the independence and prestige granted to academics and universities. There is also great need to re-evaluate and restructure the interaction between universities and industry. But scientists are not alone in this task - they can benefit from active engagement with researchers from the fields of bioethics, business ethics, and the social sciences, to clarify the perspectives and values of science and industry, and where possible bring them into alignment [10].

Continued commercial involvement in science and technology development is a reality that is unlikely to change, and this trend may well expand beyond health and biological sciences to other areas. The challenge then for scientists and academics, university administrators, and policy makers is how to deal with the good and bad of commercial involvement in science and academia.

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### References

1. J. Cohen, 'The Genomics Gamble' (1997) 275/5301 *Science* 767.
2. C. McNiven, *Canadian Biotechnology Statistics: In Support of the Implementation of the Canadian Biotechnology Strategy* (Ottawa: Science and Technology Redesign Project, Statistics Canada, March 1999), online: [http://biotech.gc.ca/archives/graphics/bh/can\\_biotech\\_stats\\_e.pdf](http://biotech.gc.ca/archives/graphics/bh/can_biotech_stats_e.pdf) (accessed: 9 September, 2002).
3. R.M. Cook-Deegan, 'National Policies Influencing Innovation Based on Human Genetics' in T.A. Caulfield & B. Williams-Jones, eds., *The Commercialization of Genetics Research: Ethical, Legal and Policy Issues* (New York: Kluwer Academic / Plenum Press, 1999) 13.
4. S. Thomas, 'Intellectual Property Rights and the Human Genome' in T.A. Caulfield & B. Williams-Jones, eds., *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues* (New York, NY: Kluwer Academic / Plenum Press, 1999) 55.
5. M.A. Heller & R.S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280/5364 *Science* 698, B.M. Knoppers, M. Hirtle, and K.C. Glass, 'Commercialization of Genetic Research and Public Policy' (1999) 286/5448 *Science* 2277.
6. M.-H. Parizeau, 'Are the Universities and Sciences Subservient to the Economy? A Summary and Analysis' (2001) 2/4 ISUMA: *Canadian Journal of Policy Research* 133, online: [http://www.isuma.net/v02n04/parizeau/parizeau\\_e.shtml](http://www.isuma.net/v02n04/parizeau/parizeau_e.shtml).
7. S. Krinsky et al., 'Scientific Journals and Their Author's Financial Interests: A Pilot Study' in T.A. Caulfield & B. Williams-Jones, eds., *The Commercialization of Genetics Research: Ethical, Legal, and Policy Issues* (New York, NY: Kluwer Academic / Plenum Publishers, 1999) 101.
8. R.S. Eisenberg, 'Proprietary Rights and the Norms of Science in Biotechnology Research' (1987) 97 *Yale Law Journal* 177, P.A. Baird, 'Patenting and Human Genes' (1998) 41/3 *Perspectives in Biology and Medicine* 391.
9. S. Lewis et al., 'Dancing with the Porcupine: Rules for Governing the University-Industry Relationship [Commentary]' (2001) 165/6 *CMAJ* 783.
10. R.K. Dhandu, *Guiding Icarus: Merging Bioethics with Corporate Interests* (New York: Wiley-Liss, 2002).

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