

# Intellectual Property and the Commercialization of Research and Development

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**ABSTRACT:** *Concern about the commercialization of research is rising, notably in testing new drugs. The problem involves oversimplified, polarizing assumptions about research and development (R&D) and intellectual property (IP). To address this problem this paper sets forth a more complex three phase RT&D process, involving Scientific Research (R), Technological Innovation (T), and Commercial Product Development (D) or the RT&D process. Scientific research and innovation testing involve costly intellectual work and do not produce free goods, but rather require IP regulation. RT&D processes involve an unrecognized IP shift from a common IP right in public goods like information and knowledge to private IP in products and other hard assets. The question then is, what kind of IP right: private or common? Since scientific research and innovation testing require openness about adverse findings, and wide, low cost diffusion of results, they require a common, inclusive IP right. Common IP is appropriate to both sharing knowledge goods and recovering the cost of production. Research is furthermore compatible with commercialization and support by other social interests. On the other hand it is incompatible with the exclusionary private IP rights that permit restrictive publication or total suppression of information. Private IP rather than commercialization conflicts with the openness requirements of scientific research and innovation testing. Commercial funding, however, is in principle compatible with research and testing, especially when regulated by a common IP right. This reflects a pragmatic view of the fundamental interconnections of knowledge and other social interests.*

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We would like to believe that most universities would support faculty members who were exerting their right to academic freedom in the face of an angry and disappointed industrial sponsor of trials that did not go their way.

*David Nathan and David Weatherall.*<sup>1</sup>

Knowledge was like water constantly flowing and difficult to dam. But it was flowing out of the organization and intellectual property laws were powerless to stop it.

*John Seely Brown and Paul Duguid.*<sup>2</sup>

## **The Commercialization of Research and Development**

John Seely Brown and Paul Duguid note the practical difficulties of restricting the flow of knowledge. David Nathan and David Weatherall are concerned about the harassment of medical researcher Nancy Olivieri by a drug company sponsor of her research, because she published adverse findings on their drug and warned her patients of related health risks.<sup>3,4</sup> The two comments highlight different aspects of the commercialization of science.<sup>5</sup> However they rest on two erroneous assumptions, namely that:

1. there is a research and development continuum; and
2. intellectual property (IP) is private property.

Both assumptions should be rejected. First, the simplistic notion of an R&D continuum should be abandoned in favour of a more complex, three phase 'RT&D' process, involving *Scientific Research* (R), *Technological Innovation* (T), and *Commercial Product Development, or Commercialization* (D). This may also help to avoid polarizing science and commerce, e.g., as R vs D. Second, IP rights are also complex. They are not only private, but common. Common IP rights are appropriate for fluid goods like information. In contrast to private property rights that allow the exclusive control of hard assets (like most technologies, commercial products, real estate, etc.), common IP rights are inclusive. They also permit individuals and groups to share use and control of assets at low costs. In contrast, private IP excludes non-owners from asset use and allows owners to set high gain-maximizing use and access prices. Common IP is compatible with the openness required in testing scientific hypotheses and genuine innovations, while private IP is not.

A shift from common to private IP rights occurs in the technological phase of RT&D processes. Since that IP shift is usually unnoticed, the view that science and commerce are opposed seems credible. On the other hand once the shift is acknowledged and common IP rights in research and innovation testing are recognized, research, innovation and commercialization can be seen as compatible collaborators. That insight reflects a deeper pragmatic principle, namely, that knowledge serves the human interest in survival and wellbeing.<sup>6</sup> The upshot is to identify some enabling conditions for a collaborative partnership between scientific research, technological innovation, and commerce.

## **RT&D Process**

The oversimplified concept of an R&D continuum is unfortunately still widely assumed, even though it disguises the mediating role of technological innovation. Only two writers, Chris Freeman<sup>7</sup> and Robert Buder,<sup>8</sup> have clearly recognized the distinct importance of technological innovation, although they too continue to speak of R&D. Use of the term, ‘RT&D process’, in this paper highlights technological innovation as a separate and distinct component. To clarify IP rights and the compatibility of science and commerce (and other social interests) one needs to consider the three phases of the RT&D process.

**Table 1. The RT&D Process**

RT&D Phases	Radical Innovation Stages	Articulation Stages	Refinement Stages
R Scientific Research Phase	R1 Revolutionary Paradigm Shift	R2 Paradigm Refinement	R3 Routine / Normal Research
T Technological Innovation Phase	T1 Radically New Technology	T2 Major Improvements	T3 Modifications & Imitations
D Product Development Phase	D1 Manufacturing Prototype	D2 Production Models	D3 Market Models

Unlike the tidy schematic in Table 1, an RT&D process is complex and dynamic. Conceptually, the three RT&D phases are distinct, while actually they interconnect and overlap. Their boundaries are fuzzy and there is no predetermined sequence.<sup>9</sup> Research, inventions, and commercialization may precede or follow each other. The three stages in each phase are presented primarily to highlight the contrast between radically new and routine ideas, technologies, and products.

## **Science**

Scientific research refers to ground-breaking or revolutionary research (R1), its refinement (R2), and routine standard research (R3), whether basic or applied, in the natural and human sciences.<sup>10</sup> Such research is driven by the search for new knowledge—regardless of researchers’ personal motives or institutional agendas; for, as S. J. Garte observes, “only in science is the complete, unmodified, and total truth... the sole necessary and sufficient yardstick of achievement.”<sup>11</sup>

Scientific research is intellectual work. It is experimental and fallible; for, as Nathan Myhrvold notes, “science is the raw material that applied research and engineering

refine into their products, [but it] is by nature an uncertain undertaking.”<sup>12</sup> (p.621) Hence it requires a self-correcting learning process which acknowledges errors as well as successes.<sup>13</sup> “Scientists”, comments John R. La Montagne, “want full disclosure of research results as soon as possible;”<sup>14</sup> (p.1724) because scientific culture demands testing and evaluation of results by one’s peers. Since adverse findings are commonplace, openness is essential to testing hypotheses and finding the truth. Indeed the more revolutionary an idea or hypothesis (R1), the higher the risk of error, and the greater the need for openness and testing.<sup>15</sup> On the other hand, the more routine (R3) the research, the more tested it is, and the more likely it will be proven true.<sup>16, 17</sup>

The scientific research phase of RT&D processes then has its own distinct characteristics and requirements, independent of innovation and commercialization. In it the search for knowledge takes primacy. “We don’t get anywhere without objective data. That’s the coin of the realm.”<sup>18</sup> It is by working to sort out valid from erroneous hypotheses and to avoid distorting biases and conflicts of interest, that science can contribute to realizing socio-economic goods such as new drugs. “If you withhold information”, S. A. Rosenberg warns, “you potentially delay progress... and the development of effective treatments; and human beings suffer and die.”<sup>19</sup>(p.10) Publication is an “ethical imperative” in research.<sup>20</sup> It is this sense of moral integrity that justifies our trust in science.<sup>21,22</sup>

Science demands openness.<sup>23,24</sup> Attempts to restrict openness or suppress research, e.g., for commercial reasons, must be resisted, for they violate scientific integrity, and make conflict between science and commerce unavoidable.<sup>25</sup> Some funding sponsors, public and private, in fact have harassed researchers whose adverse findings threaten their interests.<sup>26</sup> Commercial RT&D project sponsors that intimidate researchers have at times been supported by universities and teaching hospitals hosting the research project. Moreover institutions have sometimes had potential conflicts of interest related to potential donations from the firm funding the research.<sup>27</sup> This is what happened in Nancy Olivieri’s case, and there have been others. In 2000 the University of Toronto Faculty of Medicine withdrew its offer of a professorship to David Healy of Wales<sup>a</sup> because he claimed that research showed that many anti-depressants were being over prescribed and could lead to suicidal inclinations, a concern confirmed by the FDA.<sup>28,29</sup> His comments threatened funding promised the University by an anti-depressant manufacturer. In addition, a restrictive clause in her research contract prevented University of California researcher Betty Dong from publishing her adverse finding that the branded thyroid treatment produced by the firm sponsoring her research was no more effective than generic drugs.<sup>30</sup> Conflicts of interests between research host institutions, researchers, and project funders or supporters then are one of the most serious concerns about the commercialization of the RT&D projects.<sup>31,32</sup> Similar problems may arise with other research sponsors, whether private or public, for example, foundations, the military, or government agencies.

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a. Healy sued the University successfully in order to protect his reputation, but he did not get the academic position offered him.

Attempts by funders to litigate against researchers disclose underlying tensions between the scientific and legal modes of inquiry. “The legal process” writes J. Pfeffer, “is, at its core, adversarial, [for it] institutionalizes and legitimates conflict,”<sup>33</sup> (p.337) in contrast to an open, cooperative inquiry ethic in science. In adjudicating conflicts legal processes prefer credibility tests of witnesses over the collaborative quest for knowledge.<sup>34</sup> Many U.S. courts moreover have accepted ‘junk science’ claims from expert witnesses unqualified in the specialized technical field at issue in a case.<sup>35</sup> In its 1993 Daubert case decision the U.S. Supreme Court gave trial judges criteria for evaluating expert testimony.<sup>36</sup> Despite that welcome judgement, the problem has not disappeared.<sup>37,38</sup>

While the need to protect IP rights with regard to knowledge has been recognized, the usual mechanisms proposed are unacceptable, namely, treating knowledge as private IP or a free good. Many academics for example naïvely treat knowledge as a costless, free good. Similarly ‘techno-libertarians’ and hackers often speak of information as a free good.<sup>39,40</sup> Such views are other-worldly, inasmuch as they refuse to recognize that the production of knowledge is a form of work. As such it incurs economic costs and has social impacts.<sup>41</sup> While research was long done by amateurs of independent means like Charles Darwin, or monks like Gregor Mendel, Louis Pasteur and Albert Einstein in contrast were salaried employees—as are most researchers today, whether in business or academe. In addition research now commonly involves significant labour and equipment expenditures, especially for large scale projects.<sup>7</sup> The Human Genome Project for example involved extensive, costly computer modeling.<sup>42</sup> It could not have been done without significant financial support, public and private.<sup>43,44</sup>

Basic research in physics, biology, and genetics has largely been publicly supported by universities and governments,<sup>45</sup> although public funding for biomedical research seems to have declined somewhat.<sup>46</sup> Much research is also funded by grants from foundations, government agencies, and commercial firms.<sup>47</sup> Nor is the distribution and publication of research findings free. On the contrary communications media, whether paper or electronic, are limited, costly resources.<sup>48</sup> They involve access and use rights and charges, such as book and periodical prices, royalties, media fees, etc. To assume that knowledge is a free good is not only mistaken, it makes conflict between science and commerce inevitable and irresolvable.

In truth then *scientific research is costly intellectual work*.<sup>8</sup> (p.3-4) Universities, researchers, and project funders, public and private, all need to recover their costs.<sup>7,49</sup> The production of knowledge is not a free good. So it must be treated as IP, to secure cost recovery and recognition for the intellectual work of research. But, this poses a rarely asked question: What kind of IP right, private or common? Scientific research requires researchers openly to disclose and share information about their methods and finds. Accordingly, it must be regulated by a common IP right, not private IP; for privatization implies forms of exclusive control and restriction of publication that are inappropriate to public goods like scientific knowledge. (‘Public’ refers to open publication, not government ownership. States and government enterprises prefer secrecy and private IP almost as much as commerce.) Common IP both supports openness about adverse findings, risks as well as benefits in testing hypotheses and innovations, and cost recovery

for the intellectual work involved. It thus satisfies “the need to balance IP rights and the public good.”<sup>50</sup> In contrast private IP’s exclusionary high cost approach is incompatible with the openness required in scientific inquiry and testing innovations.

Cognitive goods call for common IP protection also because they are naturally mobile resources. Common resources however are not free goods, as some assume,<sup>51</sup> but need to be managed appropriately, as common IP. Common property rights apply to mobile resources like fisheries, water, and grazing pastures, goods which are best managed in a commons.<sup>52</sup> A commons involves community institutions that regulate both membership and manage the common resource, on a shared use, maximal access, minimal cost basis.<sup>53</sup> When common resources are treated as a free unregulated good, overuse, resource depletion and collapse become inevitable. Commons economies have been sustainable for centuries, precisely because they manage mobile, fluid goods like fish and grazing pastures as a common resource, while hard, fixed assets like arable land, buildings, and machines are regulated as private property.<sup>54</sup> So a commons economy mixes common property in fluid, mobile goods alongside private ownership of static, hard assets.

The commons approach needs to be applied to IP. Recognizing common IP rights is relatively novel; for it is not explicitly mentioned in the extensive literature sourced for this article. Information, research and knowledge are, as John Seely Brown and Paul Duguid maintain, highly fluid, inherently communicable goods. Indeed in today’s electronic communications networks information flows at the speed of light.<sup>55,56</sup> Blocking the flow of communication takes more work than enabling it; but open communication needs regulation and financing. Today we see a variety of Intellectual Commons: in the knowledge and research communities in academe and some high tech firms,<sup>2</sup> and in the relatively open, low cost communication networks constituted by phones, the mail, libraries, email and the Internet.<sup>57</sup> The electronic commons is moreover critical to today’s high tech knowledge economy.<sup>58</sup>

As a fluid good, knowledge then is in need of appropriate IP regulation, namely, by a common IP right. Fluid goods like information and research should not, therefore, be governed by a private IP right; for it supports the restrictive control and suppression of information. It is therefore inappropriate to the open communication of information required by the quest for knowledge.<sup>59</sup> Thus common IP alone is compatible with the need to publicly communicate research data, methods and findings, to recognize and reward researchers for their work, and to recover the costs of intellectual work. Indeed most researchers don’t claim ownership of their discoveries or seek patents; and many share authorship.<sup>60,61</sup>

There are two well-known forms of common IP rights: copyright and patents (which are more appropriate for technologies rather than information, research or knowledge; see the next section).<sup>62</sup> Copyrights best fit the requirements of fluid, communicable goods like information and knowledge, for they require recognition of authorship, non-mutilation of the information, and compensation of copyright owners, in return for permission to copy or reproduce their ideas at low cost.<sup>63</sup> Such IP protections are widely accepted by scientists, academics, artists and writers. While a common IP is necessary in the Intellectual Commons in which scientific research operates, a shift to Intellectual

Capital or private IP in hard assets like technologies and products emerges in the technological innovation (T) phase.

## **Technological Innovation**

Technological Innovation (T) is a distinct phase in the RT&D process that bridges scientific research (R) and product development (D), for, as Christopher Freeman and Luc Soete remark, it is “a coupling process ...a creative continuous dialogue” between science and commerce.<sup>17</sup> (pp.202-03) Innovation involves invention of a radically new technology (T1), and its refinement (T2); but applies much less to minor modifications or imitations (T3). Technological advance is now such a large scale, diverse global phenomenon that it has become a relatively autonomous social trend.<sup>64, 65</sup>

Innovations are complex. They are spawned by creative ‘animal spirits’, government incentives, management advocacy, corporate politics and social needs as much as rational efficiency.<sup>17</sup> In contrast to simple tools like knives, paper clips, canoes, etc., modern technologies require education: literacy, numeracy, and often some scientific and technical knowledge.<sup>66</sup> They embody diverse technical solutions to varied social problems, in health, food, shelter, energy, communications, transport, etc. Social ingenuity however differs from technical.<sup>67</sup> Solving different kinds of problems requires different kinds of intelligence: social, psychological, emotional, linguistic, spatial, temporal, as well as logico-mathematical and technical.<sup>68</sup>

Many new technologies: the clock, the printing press, the factory, the automobile, and the computer, have had immense, unintended social and environmental impacts, not all of them beneficial. But the newer and more complex a technology (T1, T2) or the scientific research which it incorporates (R1, R2), the less predictable its mix of benefits and risks.<sup>69,70</sup> Hence the need for adequate testing and ethical control, as is done with medical innovations like vaccinations and new pharmaceuticals—only a few of which pass clinical trials and receive FDA approval.<sup>71,72</sup> The testing of an innovation’s risks and benefits can succeed only in an open Intellectual Commons, for such testing requires full disclosure, not unlike scientific research. This lesson was tragically reinforced by the death of Jesse Gelsinger, a young patient, during the clinical trial of a new gene therapy, and by the suicides of some people on anti-depressants.<sup>73</sup>

The requirement for openness in innovation testing as well as research, e.g., about adverse findings and risks as well as benefits, calls for a common IP approach (in T1, and sometimes T2). Private IP better suits tested, proven systems ready for use and market (T3, and often T2; D1 to D3). It is here (in T1 and T2) that IP rights shift from common to private IP rights. In fact such openness has characterized several new technologies—the Internet, Linux, and genetic technologies.<sup>74</sup> There has been a tacit recognition of the need for a common IP approach to new, untested technologies and in decentralized software development.<sup>64</sup> The Presidents of several U.S. universities, plant science research institutes, and private foundations have for example expressed grave concerns about new agricultural technologies such as transgenic plant varieties, especially for subsistence and specialty crops. This has led them to propose a collective regime for

managing agricultural technology “for the public good, [and] at the same time efficiently identifying collective commercial licensing opportunities.”<sup>75 (p.175)</sup> The result has been the Public Sector IP Resource for Agriculture (PIPRA). PIPRA involves a public IP database, sharing public sector technologies, and a review of public sector patenting and licensing practice. PIPRA stands out in stark contrast to the near universal assumption that IP is private.

Patents connect common and private IP inasmuch as they require full disclosure of one’s invention in exchange for private ownership rights such as a monopoly on the technology’s use, sale and licensing. Hence many commercial organizations prefer them over trade secrets. But concerns have arisen that a recent NIH draft guideline supporting the “exclusive licensing of gene-related patents is having detrimental ..effects” on healthcare and may limit their use by researchers.<sup>76 (p.1758)</sup> U.S. patent law does however have a research exemption for academic work with patented tools or material for research purposes, free of royalties and licences. Nonetheless excessive use of patents has been criticized for having an ‘anti-commons’ effect.<sup>63</sup> Patents legalize IP and often involve litigation, so researchers tend to eschew patenting.<sup>77</sup> There are now calls to strengthen the research exemption and to allow researchers and public health agencies to freely use patented technologies such as molecules as they wish.<sup>78</sup> But few of the thousands of DNA-based patents held by 30 top U.S. universities are licensed to more than ten users.<sup>55</sup> Nearly one third have not been licensed at all. Furthermore many university based innovations are research tools. For example, Merck pharmaceuticals and the NIH are cooperating in funding patent-free transgenic mice for cancer research.<sup>79</sup>

In order to encourage the commercialization of academic research, the 1980 US Bayh-Dole Act permits American universities to own and patent new technologies developed from academic research and licence them to companies (some of their own creation), for use or sale.<sup>50</sup> As a result there have been significant increases in university patent applications (238%) and royalties (520%), notably in genomics and biotech. University / business RT&D partnerships, e.g., for cancer, heart disease, thalassemia, and Alzheimer’s research are springing up, and often sprouting university-owned biotech firms.<sup>80</sup>

Growth in high tech economies has been significantly influenced by technological advances.<sup>17, 81</sup> In fact science-based innovations have been a factor in economic growth for over a century. Radio for instance originated with Guglielmo Marconi, who exploited the latest research on the electromagnetic field in his 1896 long range radio transmitter patent application.<sup>82</sup> And high tech firms like Siemens, Bell, IBM, Pfizer, Intel, and many others have long exploited the commercial and technical possibilities of science, often allowing their scientists freedom to inquire and publish. In fact many commercial products arise from science-based innovations and many high tech firms support substantive scientific research, as shown in Table 2:



**Table 2. The *Technology Review R(T)&D Scorecard (1995 – 2000)***

Industry (Top 10 Firms)	Number of Patents. <sup>83</sup>	Science Links (References per patent) <sup>83</sup>	R&D as % of Revenue <sup>84</sup>
Aerospace	289.7	1.81	6.2
Automotive	789.4	0.83	5.4
Chemical	576.0	5.80	6.0
Computer	1858.3	2.95	8.0
Electronic	2407.8	1.61	10.7
Pharmaceuticals	542.9	35.69	18.3
Semiconductors	1024.7	1.19	34.2
Telecommunications	915.4	3.71	16.3

Table 2 gives us some idea of which industry sectors are the most scientific and innovative. The electronics industry followed by computers and semiconductors lead in total Number of Patents; but with respect to Science Links, the number of references to research publications per patent, the pharmaceutical sector is the undoubted leader, far ahead of all other industries.<sup>7,85</sup> Semiconductors, pharmaceuticals and telecommunications lead the rest in Research ‘Intensity’—that is, research and development as a percentage of gross revenue.

Technological innovation is also important in the entrepreneurial academe. Commercial ‘technology transfer’ however involves two different practices: developing innovative technologies from research, and transforming those innovations into commercial products. “Translational Research” in pharmaceuticals for example involves “interrelated and interdependent steps... from concept to clinical application, and from discovery to dissemination, translating novel scientific insights into new approaches for prevention, diagnosis and treatment of disease”<sup>86 (p.89)</sup> As one moves from Phase I to IV clinical trials one moves from small to large scale research into the risks and benefits of new pharmaceuticals; but in Phase IV drugs are now commercial products.<sup>87</sup> Thus clinical trials may combine the conflicting demands of scientific openness about research results with commercial secretiveness about product development. Such tensions raise concerns about risks to healthcare as well as scientific integrity.<sup>88,89</sup> So the commercialization process itself needs clarification.

## **Commercialization**

Commercialization (D) denotes the development of new products or of new markets for old products, with sales and profitable returns in view. Launching a new product (D1) involves significant risk, for failure is a common fate of entrepreneurs.<sup>90</sup> Nonetheless commercial research funding has doubled and tripled over recent years, although industrial contributions to research still amount to only about 4% of all academic research (8% in the U.S.)<sup>83 (p.27)</sup> RT&D has been growing in the twenty nine advanced nations in

the Organization for Economic Cooperation and Development, and now averages about 2.3% of their Gross Domestic Products.

Commerce differs significantly in its values. Science puts a premium on openness and requires common IP protections. Commercialization in contrast ‘capitalizes knowledge.’<sup>9</sup> Commercialization moreover may mean adapting scientific research to commercial interests, e.g., subordinating the communication of scientific information to gaining markets and realizing profits. Also, rather than treat information as belonging to a public Intellectual Commons, business practice is to manage it as private Intellectual Capital: “knowledge information, IP, experience—that is treated as a private asset to be put to use to create wealth.”<sup>59 (p.xx)</sup> Commercial interests therefore prefer private IP protections such as confidentiality in personal and corporate information, trade secrets, and the monopoly powers accruing in exchange for the disclosures required by patents.

Together private IP, patent applications, and commercial pressures may lead firms to delay, restrict, or suppress the publication of supported research.<sup>91,92</sup> When commercialization and privatization are combined they may put science at risk, for they may reinforce the propensity to suppress adverse findings, to bias the interpretation of data, to fabricate or destroy data, or even lead to fraud, ghost writing, or plagiarism.<sup>93,94</sup> Commercial project sponsors may seek to restrict publication of adverse research findings that would put patent applications, sales or profits at risk.<sup>95,96</sup> The commercial stress on marketing may lead pharmaceutical firms to understate risks and overstate benefits of the drugs they research.<sup>97,98</sup> Medical journal editors in fact have publicly expressed serious concerns about such pressures in the pharmaceutical industry.<sup>99, 100</sup>

The problem in my view lies more with private IP rights than commercialization, for private IP legitimizes the control and suppression of information. It bestows full, exclusive control over the publication of cognitive assets on the IP rights holders, whether they be individuals, businesses, universities, governments, foundations, or other entities. It is then the privatization of knowledge and information, not commercialization, that fundamentally clashes with the openness required for scientific research and untested innovations. The main problem is that private IP supports the suppression of information. Non-commercial interests that claim private IP rights, such as governments, the military, nuclear energy, and social advocacy groups, also seek to restrict or suppress research findings and test data adverse to their political, military, or social interests.<sup>101, 102</sup>

This may throw some light on the complex phenomenon of academic entrepreneurialism.<sup>103</sup> In the last 20 years there has been a shift in external support for biomedical research from government to commerce.<sup>47</sup> University-business alliances have been proliferating, especially in research fields of interest to high tech industries: electronics, telecommunications, chemicals, biotech, genetics, medical devices, pharmaceuticals. As commerce and academe interact more, the boundaries between the two are becoming fuzzier, notably in medicine.<sup>45,104</sup> Instead of a one-way flow of research knowledge to society, in which academe and commerce are separate institutional siloes, there is now a growing ‘spiral’ of reciprocal knowledge flows between universities, and high tech businesses.<sup>9</sup> They cooperate in developing research partnerships and collaborative networks, interdisciplinary research parks, spin-off firms created by scientists and their universities, the gearing of academic research to commercial needs,

business supported university research labs, and even the creation of new universities by businesses.<sup>105,106</sup> Entrepreneurial scientists often become project managers, working with their universities, and with interested firms, to realize the commercial promise of their research. Universities, scientists, and research organizations may share IP rights in research and related innovations.

Innovation may involve tensions, viz., between scientific integrity norms, technical design requirements, and commercial pressures.<sup>107</sup> The “uneasy alliance” between academe and commerce for instance raises normative concerns.<sup>108</sup> The most serious seem to arise when entrepreneurial universities favour private over common IP rights in research.<sup>109</sup> This takes a variety of forms: restructuring research groups to capture exclusive IP rights, creating spin-off firms to maximize the return on that IP, claiming private ownership of inventions developed by faculty, or negotiating royalty sharing agreements with faculty. They may conflict with scientific integrity. Twenty-seven percent of university innovation licenses, a survey reports, allow the deletion of information from papers before submission; and forty-four percent seek publication delays, on average of about four months. Project partner firms too may seek to control publication of research from labs jointly owned with universities.<sup>9</sup> It has moreover been estimated that from thirty to fifty percent of research contracts submitted by commercial sponsors have restrictive publication clauses.<sup>100</sup> A 1994 Carnegie Mellon survey reported that eighty-two percent of biotech and pharmaceutical firms require scientists to keep results confidential for months, so as to facilitate patent filing.<sup>20</sup> Thirty-five percent of the scientists surveyed had signed agreements allowing sponsors to delete information from publications. Fifty three percent of the researchers agreed to publication delays (usually less than a year), mostly to give funding organizations time to apply for patents or develop a commercial product. Even worse, researchers may be intimidated by commercial funding sponsors and universities, as happened in the Olivieri and Healy cases.

In addition, the nexus between commercialization and innovation is tenuous. Commercial success is not the same as scientific or technical success; nor does commercialization entail innovation. Technologies, whether new (T1, T2) or minimally modified (T3), usually need to be redesigned in order to be commercialized: first as manufacturing prototypes (D1), and then for high volume production and sale (D2, D3). Even then new products may not embody new technologies (T1 to T3) or recent research (R1 to R3).<sup>7,18</sup> Consumer preference, competitive pressures, cost effectiveness, and profitability concerns often override scientific and technical considerations. Thus there is ‘product differentiation’ in automobiles. VHS won out over Beta videotape, just as Microsoft’s operating systems beat Apple’s Macintosh system; and ‘natural’ or ‘organic’ drugs are inadequately tested and of dubious efficacy.

While pharmaceutical firms do support much research, only about two percent of ‘new’ drugs offer a “real advance” in treatment (T1, T2), while five percent “provide minor benefits” (T3) and 80% “provide no advantage over existing treatments.”<sup>110</sup> Patents moreover may reflect the inventive output of firms rather than genuine innovations.<sup>17 (p.112f)</sup> Indeed many patents are for modifications of existing drugs, generics, and ‘me-too’ copies of competing drugs (the subject of Betty Dong’s contract

research).<sup>111</sup> U.S. pharmaceutical firms claim to spend \$24 billion on RT&D.<sup>73</sup> The industry estimates that the average cost of developing a new drug to be over \$500 million, with only one third recovering their development costs. But two thirds of pharmaceutical industry RT&D funding supports the transfer of research findings into technologies with commercial potential as products. And the industry spends so much more money on marketing than research that ad agencies are now acquiring clinical research companies.<sup>112</sup>

New technologies, like research hypotheses, also need testing and open disclosure of all findings, however adverse, so as to reduce risks and ensure benefits. In fine, neither research nor innovation (T1, T2) is free or effortless. On the contrary the development of new technologies involves significant risks, effort and costs.<sup>17</sup> Nor is commercializing innovations certain or cheap. Science-intensive innovations tend to incur high front end research and technical development costs, but as commercial products they often yield increasing returns in modern markets, for example, new pharmaceuticals before competing drugs or generics come into the market.<sup>78</sup> On the other hand, radically new technologies may seriously disrupt businesses based on older systems.<sup>113</sup> No wonder firms opt for a defensive strategy of minimal, imitative innovations (T3) to reduce their costs and market risks.<sup>7</sup>

Despite normative tensions and conflicts, commercialization is not itself incompatible with research; for commerce, like other supportive institutions such as states and foundations, also funds research and innovation. Such interests are not therefore fundamentally incompatible with openness in research and innovation testing. However those institutions should opt for common IP rights, rather than private IP, with regard to the knowledge and information whose production they support; for only a common IP right enables both openness and the recovery of often high RT&D costs. This exemplifies a pragmatic view of the depth interconnection of knowledge and interests.

## **Pragmatism, Science and Commerce**

This critical re-examination of outdated assumptions about R&D and IP, has disclosed the complexity of the RT&D processes and the need for common as well as private IP rights. Taken together research, technological innovation and commercial product development (R, T and D), reflect a key division of labour in high tech society. Research is not technological innovation; and both differ from commercialization. Their interests are different, though often complementary. While scientists are interested in knowledge and innovators in technically efficient, reliable systems, businesses focus on developing products and markets, cost effectiveness and profits.

At the same time commerce, academe, government and other supporting institutions fund research and innovation. To that extent their interests are compatible with those of researchers and innovators. However, though scientific research is costly and requires supportive funding, i.e., it is not a free good, the knowledge and information it generates should not be treated as private IP, for that encourages secretiveness and the suppression of information. It is incompatible with the need for openness with regard to adverse as

well as supportive findings, risks as well as benefits, whether in scientific research, technology testing, or commercializing products. Moreover, knowledge is a fluid and public good, not a private asset. Public goods are best regulated under a common IP right because common IP rights alone can both protect research and innovation and also support the recovery of the RT&D project costs.

Elucidating RT&D processes and their implications for both common and private IP rights is then critically essential to preventing normative conflicts between science and commerce, whether in the entrepreneurial academe or in high tech firms. For such clarification opens up an inclusive social space in which the different interests of scientific research and its funding sponsors, private or public, commercial or state, are seen as compatible. Scientific knowledge, technological innovation, and commercialization can and often do collaborate in RT&D processes, to their mutual benefit. Indeed communication networks and markets both presuppose the relatively open exchange of information and goods.<sup>59</sup> Other interests, public and private, also support research: governments, foundations, and other social organizations. Indeed knowledge has been deemed important by social elites for millennia, from the reliance of pharaohs on priestly scribes, the medieval church on the university, and the modern British and French states' 17<sup>th</sup> century founding of the *Royal Society* and the *Academie Francaise*.<sup>114</sup> In addition academic scientists have been involved with industry since the 19<sup>th</sup> century, and with governments long before. In previous decades universities' main 'outside' research funding partners were governments, notably in the fields of agricultural, medical and military RT&D; and they still are in many nations.<sup>83</sup>

The fundamental compatibility of research and its supporting organizations reflects a deeper pragmatic philosophical thesis, namely that knowledge is useful to humanity. As Charles Saunders Peirce, the founder of pragmatism and himself a practicing scientist, cogently argued, knowledge has "behavioural implications" useful to "the conduct of life."<sup>115(p.273)</sup> Indeed "the meaning of an intellectual conception is the practical consequences that would result ...from the truth of that conception." Not only do organizations seek to constrain knowledge when it threatens their interests, as evidenced in the Olivieri, Healy and Dong cases, but knowledge itself can be used to criticize abuses of power, as critical social theorists maintain.<sup>116</sup> Indeed human intelligence, as Darwin argued, evolved with advanced "mental powers" so as to serve the species' fundamental interest in survival and wellbeing.<sup>117</sup> Only such cognitive powers, not error, ignorance, stupidity, 'post-modern' relativism or radical skepticism, can explain the sciences' impressive cognitive achievement.<sup>16</sup>

In conclusion I would like to suggest three enabling conditions for an ethical, collaborative partnership among scientific researchers, technological innovators, and supportive commercial or social interests. All should:

1. Reduce health, environmental and social risks to acceptably low levels;
2. Respect scientific integrity and openness;
3. Respect common as well as private IP rights.

The first two are fundamental, and the first would ultimately override the second, they usually interact symbiotically. Together they outrank other considerations. The third enables collaboration among scientists, innovators, commerce and other supporters of RT&D processes. Complying with all three conditions facilitates those collaborative relations between knowledge and human interests which are essential to a successful and sustainable high tech civilization.

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