

1 **Chapter 54**
 2 **Technology Transfer and Its Role in the Practice of Reproductive**
 3 **Endocrinology and Infertility**

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5 **Abstract** This chapter is very different from the other
 6 chapters in this book. Rather than addressing specific repro-
 7 ductive endocrinology and infertility diagnostic and thera-
 8 peutic needs and situations, it is intended to help clinicians
 9 who come up with ideas that have the potential to improve
 10 the practice of reproductive endocrinology and infertility
 11 ~~and~~ translate those ideas from bench to bedside.

12 **Keywords** Technology transfer • Intellectual property • Patents
 13 • Copyrights • Trademarks • Trade secrets and mask works

14 **54.1 Technology Transfer**

15 Technology transfer means the transfer of a technology from
 16 one party to another. So, when for example Hewlett Packard
 17 or IBM establishes a factory in Singapore or Bangalore to
 18 manufacture a product developed in the US, it involves a
 19 transfer of technology, from one country to another, but gen-
 20 erally the technology stays within the same company.

21 In the US, however, the term “technology transfer” has
 22 come to mean the transfer of a technology developed at an
 23 academic institution, often with federal or philanthropic
 24 funding, to a company which can secure the necessary private
 25 funds to develop the technology, secure any necessary regu-
 26 latory or standards approvals to market the product and then
 27 ~~to~~ manufacture and bring the product to market.

28 Academic institutions have developed offices and
 29 resources of varying degrees of sophistication to facilitate
 30 this process, which we will discuss later.

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54.2 **A Brief History of Technology Transfer** 31
in the United States 32

33 Until 1980, if an academic researcher made an invention with
 34 federal funding, the government owned the resultant patent
 35 rights. The government had a firm policy that it would not
 36 grant exclusive licenses to inventions it owned, but would only
 37 license them nonexclusively. This meant that there was little
 38 incentive for companies to make the investment necessary to
 39 develop academic technologies because once they had made
 40 the investment and proved the viability of the technology, their
 41 competitors could then obtain a license on the same terms
 42 without having to make the same high risk investment.

43 As a result, in 1978 the government owned 28,000 academic
 44 patents and had licensed fewer than 4% of them. Inventions
 45 reported to NSF and NIH ~~are~~ declining even though federal
 46 funding of research was booming. And perhaps worst of all,
 47 companies would talk of research being “tainted” if it had
 48 received federal funding because of their fear of the govern-
 49 ment being able to grant nonexclusive licenses if it owned the
 50 patent rights (or even jointly owned them by virtue of having
 51 provided part of the funding to develop the technology).

52 Also at this time, the US economy was perceived as being
 53 in trouble under the double burden of high interest rates
 54 and high oil prices, coupled with a loss of leadership of
 55 manufacturing efficiency to Europe and Japan.

56 Senators Robert Dole (R, KS) and Birch Bayh (D., IN)
 57 led a bipartisan effort to help restore the vitality all of the US
 58 economy by removing the barriers to widespread integration
 59 of academic innovation into the mainstream economy.

60 In 1980, Congress enacted the Bayh–Dole Act [1] which
 61 allowed US universities, teaching hospitals, research institutes
 62 and small businesses to have the automatic right to take title
 63 to inventions made with federal funding.

64 The Act imposed a few requirements on institutions:

- 65 • Institutions ~~are~~ required to share any income they receive
 66 with inventors
- 67 • Institutions may only use the remainder on research and
 68 education

- 69 • Institutions ~~are~~ expected to file patents on inventions they
- 70 elect to own
- 71 • Institutions ~~are~~ encouraged to collaborate with commercial
- 72 concerns to promote the utilization of inventions arising
- 73 from federal funding
- 74 • Institutions ~~are~~ expected to give licensing preference to
- 75 small businesses
- 76 • Products ~~patented~~ in the US ~~are to~~ be manufactured in
- 77 the US
- 78 • The government retains a nonexclusive license to practice
- 79 the patent throughout the world
- 80 • The government retains march-in rights to grant licenses
- 81 in the public interest ~~to check~~ if the invention is not being
- 82 exploited

83 Little was visible for quite some time. Institutions estab-
 84 lished offices of technology transfer to seek patent protec-
 85 tion on these inventions and license them to existing and
 86 new businesses for development and commercialization,
 87 but there did not seem to be much impact on the economy
 88 at large. The 1980s were still a difficult time for the US
 89 economy, with oil prices reaching record levels in 1982 that
 90 were only exceeded in inflation-adjusted terms in the sum-
 91 mer of 2008, and with the US semiconductor industry sus-
 92 taining heavy losses and loss of market share in DRAM
 93 memory chips.

94 As recently as April 1992, the cover story of Business
 95 Week trumpeted gloom and doom and called on the govern-
 96 ment to establish an industrial policy. It said: “The very
 97 phrase rattles the teeth. It implies bureaucracy. It suggests
 98 that government will pick winners and losers. Done badly, it
 99 would certainly hurt America. But with the Cold War over
 100 and the global economy taking shape, American needs to
 101 shore up its competitiveness. How? Certainly by investing in
 102 education and infrastructure. But that’s not enough. We must
 103 recharge the knowledge base – the basic science and technol-
 104 ogy that are the foundation of an advanced industrial society.
 105 Perhaps we should call it a “growth policy.”

106 Just six months later, Business Week was trumpeting an
 107 entirely different message. “Hot Spots” was the theme off
 108 the issue with the subtitle “America’s New Growth Regions.”
 109 Inside it was clear that the recharging of the knowledge base
 110 had already taken place. A map showed a series of clusters
 111 from Ceramic Corridor in Upstate New York to Laser Lane
 112 in Orlando, Florida to optics Valley in Tucson, Arizona and
 113 up to Boomtown Boise in Boise, Idaho. The map stated that
 114 600,000 people held high-tech jobs in these places.

115 As notable as anything was the omission of the tradi-
 116 tional high-tech clusters of Route 128 in Boston, Research
 117 Triangle in North Carolina, and Silicon Valley in California
 118 from the map.

119 The article correctly identified the ingredients for a high
 120 tech cluster that hold true today, starting with a major
 121 research university:

- A major research university 122
- Quality of life 123
- Build on local industry 124
- Cooperation between local university, business and 125
government 126
- Technology transfer from the university 127
- Funding sources – state, venture capital, angels 128
- Incubators. 129

54.3 The Impact of Technology Transfer 130

131 Since 1991, the Association of University Technology
 132 Managers has published an annual survey which has quanti-
 133 fied the magnitude of the US’s technology transfer enterprise
 134 [2]: For instance, in 2006, institutions

- Managed 18,874 new invention disclosures 135
- Filed 15,908 total U.S. patent applications 136
- Had 3,255 U.S. patents issued 137
- Signed 4,963 new licenses 138
- Managed 12,672 licenses and options that are yielding 139
active income. 140
- Had 697 new products introduced to the market in 2006 141
from active licensees; 142
- Introduced more than 4,350 new products into the market 143
in the nine years from FY1998 to FY2006. 144
- Launched 553 new startup companies in 2006 and 5,724 145
since 1980. 146

147 Academic technology transfer generates new products in
 148 a broad range of sectors of society and industry, but has had
 149 a particular impact on two sectors:

- Healthcare, reflecting the large amount of federal funding 150
for healthcare research 151
- The Internet, reflecting its academic origins. 152

153 A recent study [3] quantified the considerable contribution
 154 to improve public health through the discovery, patenting,
 155 licensing and successful development of over 130 small mole-
 156 cule and biological drugs, vaccines and in vivo diagnostics,

157 Some of the contributions of academic institutions to the
 158 development of the Internet are shown in Table 54.1.

Table 54.1 Components of the internet that originated in academic institutions t1.1

Component	Originating institution	
World Wide Web	European Organization for Nuclear Research (CERN)	t1.2
Mosaic (Internet Explorer)	University of Illinois Urbana Champaign	t1.3
Eudora	University of Illinois Urbana Champaign	t1.4
Yahoo	Stanford	t1.5
Lycos	Carnegie Mellon	t1.6
Akamai	MIT	t1.7
Google	Stanford	t1.8
		t1.9
		t1.10
		t1.11

159 It is not surprising therefore that some institutions have
 160 garnered enormous returns from technology transfer. The
 161 2006 AUTM Licensing Activity Survey showed that overall,
 162 US academic institutions received almost \$2 billion in licensing
 163 income. However, this income is highly concentrated in a small
 164 number of institutions who have had one big success, frequently
 165 a drug – the so-called “big hit”.

166 **54.4 Intellectual Property**

167 Technology transfer starts with intellectual property.
 168 Intellectual property is a blanket term for a number of
 169 different mechanisms for protecting the results of intellectual
 170 activity. The most common of these, and the most important
 171 in life sciences research, is the patent system. Other important
 172 mechanisms are copyrights, trademarks, trade secrets and
 173 mask works.

174 It may seem antithetical to the spirit of science to try and
 175 sequester knowledge, and certainly a number of the critics of
 176 technology transfer make that argument. However, this view
 177 reflects a fundamental misunderstanding of the intention and
 178 purpose of the patent system, which has always been to pro-
 179 vide incentives to inventors to fully disclose their inventions to
 180 the world so that others may build on them, in return for the
 181 inventor being given a period of exclusive use of their innova-
 182 tion, rather than holding the knowledge close to their chest and
 183 practicing it in secret. By properly utilizing the patent system,
 184 a scientist can publish his or her findings and advance the body
 185 of scientific knowledge, while reserving for him or herself the
 186 exclusive commercial use of those findings. Indeed, a recent
 187 study of publications in Nature Biotechnology found that
 188 almost 50% of articles in that journal between 1997 and 1999
 189 had a counterpart issued US patent by 2006, a phenomenon
 190 the author termed the Paper-Patent-Pair [4].

191 That said, a minority of academic scientists make the
 192 effort to commercialize their scientific findings. A study of
 193 3,342 science faculty at six universities over 17 years [5]
 194 found that almost 65% of faculty never disclose an invention,
 195 another 22% disclose an invention once or twice in their
 196 careers and fewer than 15% are prolific users of the commer-
 197 cialization process. The data are shown in Table 54.2.

12.1 **Table 54.2** Faculty invention disclosure rates

12.2	Number of disclosures	%
12.3	Never disclose	64.2
12.4	Disclosed once	14.8
12.5	Disclosed twice	7.6
12.6	Disclosed three to five times	11.4
12.7	Disclosed eight or more times	2.0

Table 54.3 Relationship of faculty performance to industrial research support

Variable	No. of publica- tions	Teaching time	No. of service activities	Publication- trends score
No industrial support	10.1	16.6	1.8	2.1
Industrial support	14.6	16.0	2.3	4.2
1–33%	16.8	17.7	2.8	5.0
34–66%	16.4	19.3	2.2	5.3
67–100%	12.1	15.8	2.1	2.5

198 Research has also shown that faculty who are involved with
 199 commercialization are better faculty, as measured by publication
 200 rate and participation on faculty committees than faculty who
 201 are not involved with industry [6]. The data are shown in
 202 Table 54.3. This relationship holds true until industrial support
 203 accounts for more than 2/3rd of total support for the lab.

204 **54.5 Who Owns Your Invention?**

205 Who owns your invention will have a lot to do with how it
 206 gets handled and how much you will benefit from it.

207 If you work for a company, you will have undoubtedly
 208 been required to sign an invention agreement when you join
 209 the company, in which you agreed to assign any inventions
 210 you made to the company.

211 If you work for a university or an academic medical center
 212 (AMC) which is affiliated with a university, then you will have
 213 signed also an invention agreement, commonly known as a
 214 patent policy or patent policy agreement, in which you also
 215 agreed to assign ownership of your inventions to the University
 216 or AMC. Unlike a company agreement, where you will most
 217 likely have been given “\$1 and other good and valuable
 218 consideration (such as keeping your job)” ~~In contrast to the
 219 company agreement where you have not been promised any
 220 share in the profits made from your inventions, the University~~
 221 patent policy agreement will probably include a detailed
 222 description of just how much of the university’s income you
 223 will receive. As we noted earlier under the discussion of the
 224 Bayh–Dole Act, it is a legal requirement that the inventor share
 225 in the income. Theoretically, the university could have a sepa-
 226 rate policy for income from inventions that were not federally
 227 funded, but the majority of institutions have a single policy.
 228 Typical rates are from 25–35% though some institutions have
 229 tiered distributions which give a higher percentage of the early
 230 income to the inventors and lower percentages as income
 231 increases. There may be an additional percentage allocated to
 232 your own laboratory. If there is no lab share, there will undoubt-
 233 edly be a share allocated to your department or college, and
 234 you should negotiate with the chair/chief/dean for somewhere

235 between one third to one half of this department/college share
236 to be allocated to your lab account.

237 There will be an office of technology transfer/licensing/
238 industrial relations to whom you should submit the invention
239 disclosure and which will manage the process for you, with
240 your enthusiastic support.

241 If you work for a community hospital, a for-profit hospi-
242 tal, a nonprofit HMO, a group practice or in private prac-
243 tice, then it is likely that the total basis for your employment
244 is clinical practice with no research component to it. In
245 those circumstances, there will likely be no policies on
246 inventorship and ownership, in which case you will be free
247 to pursue (and pay for!) your inventions entirely by and for
248 yourself.

249 **54.6 The Invention**

250 In the course of your clinical practice, you will frequently
251 identify an unmet medical need, something that you would
252 buy and use if it were available, but which you find is not
253 available commercially. It may be a new diagnostic test, a
254 new instrument, an improvement on an existing instrument,
255 a new drug, a new use for an existing drug, a combination of
256 two existing drugs, a new way of delivering or dosing an
257 existing drug, and so forth.

258 One thing that is no longer worth patenting is a surgical
259 procedure. In the early 1990s, Dr. Samuel Pallin filed a patent
260 infringement suit against Dr. Jack Singer alleging
261 infringement of U.S. Patent No. 5,080,111 on a patented
262 surgical technique for use during cataract surgery [7]. The
263 case caused widespread outrage both within the medical
264 profession, among the public and in Congress. The 1996
265 Omnibus Appropriations bill, Public Law 104-208, con-
266 tained a section, which limited the legal remedies available
267 for infringement of patents on medical procedures. That
268 said, if you identify a new surgical procedure that you think
269 has merit, the way to extract value from it would be to
270 develop and patent a new instrument or machine to carry out
271 the procedure.

272 **54.7 Obtaining a Patent**

273 The basic criteria for obtaining a patent are that the invention
274 must be:

- 275 • Novel
- 276 • Useful
- 277 • Nonobvious; and
- 278 • Adequately described.

54.7.1 Novelty

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Novelty means that the invention has not been identically
described in the literature anywhere in the world, or put on
sale in the country in which patent protection is being sought.
In the US or Canada, an inventor can publish his or her inven-
tion and still apply for a patent within a year, and in Japan
within six months. In the rest of the world, a patent examiner
somewhere must be the first person to learn about an inven-
tion for it to be patentable, so a US inventor who takes advan-
tage of this one-year “grace period” will lose the opportunity
for worldwide protection. Fortunately, the advent of provi-
sional patent applications in the US has greatly facilitated the
patent application process for academic inventors, by reduc-
ing substantially the time and effort needed to file an initial
patent application.

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54.7.2 Utility

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Utility means that the inventor must disclose a use of his
invention. He or she doesn't have to disclose all the uses and
doesn't even have to disclose the most important use he or
she knows of. These can be added at a later stage.

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54.7.3 Nonobviousness

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Nonobviousness means that the invention could not have
been anticipated by putting together two existing inven-
tions. In many academic inventions, these are some of the
most difficult arguments made by the patent examiner to
overcome. A patent examiner frequently combines references
from widely different areas of science and claims that these
make the invention obvious.

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This has always been one of the most difficult patent
examiner objections to overcome, and the examiners' hands
were strengthened by a 2007 Supreme Court decision, *KSR*
v. Teleflex, which eliminated a relatively inventor-friendly
test for determining obviousness.

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54.7.4 Adequately Described

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You must disclose your invention in sufficient detail that one
ordinarily skilled in the art can understand it. For a medical
invention this would mean say, another OB/GYN, not just
your 10 closest academic competitors in the world.

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You must also disclose the best way you know of to carry
out the invention at the time you file the patent application – the

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319 “best mode”. You don’t have to file updates if you subsequently
320 learn even better ways of carrying out the invention.

321 You do not even have to actually carry out the invention
322 ~~have~~ proven that it works. You can file a predictive patent
323 application, politely called a “constructive reduction to prac-
324 tice”. For example, the University of Rochester obtained a
325 patent (US Patent 6,048,850 “Method of inhibiting prosta-
326 glandin synthesis in a human host”) claiming all uses of
327 drugs which selectively inhibited cyclooxygenase 2, but not
328 cyclooxygenase 1. At the time the patent was filed, the uni-
329 versity only had possession of two cell lines, one of which
330 stably expressed Cox 1 and the other of which stably
331 expressed Cox 2. The rest of the patent is devoted to predict-
332 ing how one would use these two cell lines to identify com-
333 pounds which inhibit Cox 2, but not Cox 1. Rochester
334 subsequently sued Pfizer claiming infringement of the patent
335 by Celebrex [8] and after an enormous (and enormously
336 expensive) legal fight, the patent was ~~later~~ found invalid for
337 lack of enablement.

338 **54.7.5 Patent Systems**

339 There are two patent systems in the world:

- 340 • First-to-invent
- 341 • First-to-file

342 The US is now alone in operating on a “First-to-invent”
343 system. In this system, if two inventors can show that they
344 are entitled to be awarded the same patent, then the patent
345 will be awarded to the inventor who can show they were the
346 first to make the invention. The process by which this deter-
347 mination is made, if there are two competing inventors, is
348 called an “interference”. It is an adversarial process conducted
349 not in court, but before a special board of the Patent Office
350 – the Board of Patent Appeals and Interferences. Their deci-
351 sion is appealable to the US Federal District Court and from
352 there to the US Court of Appeals of the Federal Circuit, the
353 national court of appeals for patent cases. An interference is
354 an expensive process and can take a long time to complete –
355 the battle between Shmuel Cabilly of City of Hope Hospital
356 in Los Angeles and Michael Boss of Celltech in the UK over
357 coexpression of both chains of a monoclonal antibody in a
358 single cell – an enormously valuable patent, that is required
359 in the production of any recombinant antibody – took 18
360 years from application to a final (negotiated) settlement after
361 appeal to Federal District Court. (The patent has since been
362 invalidated on re-examination by the US PTO, a decision
363 itself being appealed to the Board of Patent Appeals and
364 Interferences! [9], so the fight still isn’t over!).

365 The rest of the world operates on a first to file system. In
366 this system, if two inventors can show that they are entitled

to be awarded the same patent, then the patent will be
awarded to the inventor who first filed their application some-
where in the world.

There are other differences between the two patent
systems. Most notably, as noted earlier, outside the US “absol-
ute novelty” applies – a patent application must be filed
before the invention is published anywhere in the world. In
the US and Canada, the inventor has 12 months from when
they publish enabling details of the invention to file a patent
application. In Japan, under some circumstances, the inventor
has 6 months from publication to file a patent application.

What this means is that even the US applications should
be filed before details of the invention are published, or else
worldwide rights will be lost. In the past, this presented aca-
demics with a dilemma – should they risk losing scientific
credit for being first to publish while they took one to two
months to file a patent application, or should they publish
first, take advantage of the one year “grace period” and file
after publication and be content with the US rights only?
Happily, since 1995, as discussed in the next section, a new
form of patent application has been available that can be filed
much more quickly and now it is possible to “have your aca-
demic cake and eat it too.”

Another important difference between the US and
European systems is that patents cannot be obtained for
methods of treating people (e.g., a new use for an existing
drug). Patent attorneys can formulate alternative ways to
claim the invention to overcome this limitation.

54.8 Types of Patent Application

You will encounter a number of different types of patent
applications.

54.8.1 Provisional Patent Application

Provisional patent applications have only been available in
the US since 1995 when the GATT treaty came into effect
[10]. A provisional patent application may be filed by an
inventor by him or herself or their technology transfer office
for a filing fee of \$100 plus an Express Mail fee. A provi-
sional application doesn’t have to include any claims or even
name any inventors. It must merely enable at least as broad a
scope as the inventors ultimately wish to claim. A provisional
patent application merely plants a stake in the ground and
gives the inventor a year to convert the provisional applica-
tion to a full utility application or PCT application and gain
the benefit of the earlier filing date. If the inventor does noth-
ing, then the provisional application dies and is never seen.

412 A significant benefit of a provisional application is that the
 413 one-year duration does not count toward the maximum 20
 414 year lifetime of a utility application from initial filing. While
 415 nothing happens during that year toward examination and
 416 issuance of a patent, this de facto extension of the term of the
 417 patent is very valuable with life sciences invention, which
 418 will have to go through a protracted period of development
 419 before they can be commercialized. Pharmaceutical compa-
 420 nies frequently prepare full utility applications on their
 421 inventions, but file them as provisional applications and then
 422 merely refile them as utility applications at their one-year
 423 anniversary.

424 **54.8.2 Utility Application**

425 A utility patent application is the main sort of US patent
 426 application and is intended to lead to issuance of the most
 427 important category of US patent, the utility patent (the others,
 428 which are encountered much less frequently are design
 429 patents and plant patents – only asexually reproduced plants
 430 such as potatoes).

431 Under the American Inventors Protection Act of 1999,
 432 US applications have been published since March 15, 2001.
 433 Previously, the US patent applications were confidential until
 434 the patent was issued.

435 **54.8.3 PCT Application**

436 The Paris Convention of 1883 allowed inventors a year to
 437 file corresponding foreign applications after the initial filing
 438 in one of the signatory countries. Today 169 countries are
 439 signatures to the Paris Convention.

440 PCT is an abbreviation for the Patent Cooperation Treaty
 441 and is the primary form of international patent application. The
 442 Patent Cooperative Treaty came into effect in 1978 and allows
 443 for a single worldwide filing to fulfill the Paris Convention
 444 requirements. There are currently around 133 signatories and
 445 they include all major economies except Taiwan, Malaysia,
 446 Thailand, Uruguay, and Venezuela. PCT applications are typi-
 447 cally filed a year after the initial (“priority”) application.

448 A PCT application can be filed in any language though
 449 effectively the choice is limited to Arabic, Chinese, English,
 450 French, German, Japanese, Russian or Spanish, and Dutch,
 451 Korean and certain Nordic languages. The overwhelming
 452 majority are filed in English.

453 A PCT application can undergo a preliminary examina-
 454 tion at the international level, which can be helpful. A PCT
 455 application is published 18 months after its priority date, or
 456 six months after the PCT filing date.

After a further 12 months (i.e., 30 months from the prior-
 ity date), the PCT application expires and applications must
 be filed in individual countries.

54.8.4 National Phase Patent Applications

These are applications in individual country patent offices or
 regional patent offices such as the European Patent Office.
 Academic institutions will generally not file outside the US
 unless they have a licensee to reimburse the costs.

Most licensees other than the very largest pharmaceutical
 companies will only file patent applications in developed
 countries. A typical group of foreign counterparts might
 include:

- European Patent Office (“EPO”)
- Japan
- Australia
- New Zealand
- Canada

The next tier of countries might include China, India and
 South Africa.

54.8.5 European Patent Office

The European Patent Office is based in Munich, Germany
 and examines patents on behalf of 34 (as of January 1, 2008)
 European countries. All western European countries cur-
 rently belong, and the countries formed by the breakup of the
 former Yugoslavia recognize EPO patents.

All examination and approval of patents, including the
 opportunity for companies to object to the issuance of a pat-
 ent that has been approved for granting, occurs at the EPO
 level. The EPO doesn’t issue patents – this is still done at the
 individual country level, and translation costs were substan-
 tial. In October 2000, the London Agreement substantially
 reduced the number of translations required. The London
 Agreement came into effect on May 1, 2008.

54.9 Prosecuting a Patent Application

When the patent attorney has finished working with you to
 prepare the patent, he or she mails it to the patent office using
 Express Mail. At the patent office, it is assigned to a patent
 examiner, who probably has a backlog of 120 or so cases.
 Examiners have to work through their backlog and dispose
 of eight cases per two week period.

497 Eventually, the invention reaches the top of the examiner's pile
 498 and the examiner reads it for the first time. The examiner's
 499 normal first reaction to a patent application is to decide that
 500 there are actually two or more separate inventions contained
 501 in the application and to split it up into two or more separate
 502 applications. Since the patent lies in the claims, the examiner
 503 may say something like: "The first invention is claims 1–4
 504 and 6–10; the second invention is claims 5, and 11–15, and
 505 the third invention is claims 16–26." This is called a restriction
 506 requirement. The inventor now has to pick the application
 507 he/she wants to prosecute first. The inventor will normally
 508 pick either:

- 509 (a) The invention they think they have the best chance of
 510 getting issued; or
- 511 (b) The invention that they want the patent issued first for
 512 commercial reasons.

513 The inventions that the inventor doesn't pick sit at the patent
 514 office, and the inventor can come back and start prosecuting
 515 them when the one they prosecute first is allowed. The so
 516 sidelined inventions are called "Divisional applications."

517 After the inventor, through their attorney, picks which set
 518 of claims to prosecute, the substantive prosecution will com-
 519 mence in earnest. The next communication from the Examiner
 520 is likely to be a rejection of all claims, for a combination of
 521 prior art, obviousness lack of enablement or lack of specific-
 522 ity, and citing references. The attorney will have views on
 523 some of the Examiner's arguments and will write to the inventor
 524 laying out the Examiner's concerns, his proposed responses
 525 and asking for the inventors' views. It is critical that the inventor
 526 be engaged in the process, read these somewhat dry pieces of
 527 correspondence (the communications from the Examiner tend
 528 to be particularly dry), read the references and help the
 529 attorney mount the strongest possible response.

530 The prosecution will go back and forth in this way, with
 531 the attorney and the inventor hopefully whittling away at the
 532 Examiners' objections. An inventor has a right to talk to the
 533 Examiner, either by phone or in person at the Patent Office in
 534 Washington. This is often an effective way to overcome
 535 objections and get an allowance – it makes a very strong
 536 statement to the Examiner that the inventor truly believes
 537 they're entitled to something – and the inventor should be
 538 prepared to put in the effort to take advantage of such an
 539 opportunity if it is offered.

540 Hopefully, the Examiner will eventually be convinced and
 541 will mail a "Notice of Allowance" to the attorney. At that
 542 point, the attorney will pay the Issue Fee and about three
 543 months later, on a Tuesday [11], the patent will issue.

544 In the interim between when the fee is paid and the patent
 545 issues, it is time to go back and revisit the Divisional applica-
 546 tions that were left on the table at the outset of the process.
 547 If the inventor wants to pursue them, the additional applications
 548 must be filed before the patent issues.

54.10 How Much Does it Cost to Get a Patent?

549 How long is a piece of string? As any attorney or economist
 550 likes to say: "It depends". However, in overview, healthcare
 551 inventions tend to be relatively expensive. The examples are
 552 highly technical, and the inventor will generally want to
 553 claim much more broadly than the specific examples they've
 554 carried out.
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556 There are three elements to the cost of obtaining a
 557 patent:
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- 559 • Attorney's fees
- 560 • Official fees
- 561 • Translation costs

562 Attorneys charge by the hour, in increments generally of
 563 6 min (0.1 h). As of this writing in early 2008, partners at
 564 major law firms are charging \$500–\$750 per h; associates
 565 \$250–\$475 per hour, technical specialists with PhD's \$125–\$400
 566 per hour, depending on experience. In New York City, rates
 567 may be even higher. Smaller firms are variable. Some may
 568 have very similar rates overall. Typically, the partners' rates
 569 will be lower, but the associate and technical specialist's rate
 570 may be essentially the same.

571 By retaining an attorney and asking them to do something
 572 for you, you are essentially giving them a blank check – you
 573 are saying "Take as long as you need to get this job done,
 574 multiply by your hourly rate and send me the bill and I'll pay
 575 it." To avoid unpleasant surprises, it's advisable to ask the
 576 firm to cap the fees, by asking them to commit to a "Not to
 577 exceed" figure. For repetitive matters such as writing a pat-
 578 ent, firms have a lot of experience and will generally be ready
 579 to do this.

580 Official fees are reasonable in the US. The US PTO
 581 charges modest fees and gives a 50% discount to small com-
 582 panies (less than 500 employees), not-for-profits and indi-
 583 viduals. Once a US patent is issued, maintenance fees are
 584 due at 3½, 7, and 11½ years. ~~The fees increase at each~~
 585 ~~milestone.~~

586 Foreign patent office fees tend to be higher. PCT filing
 587 costs are \$3,000–\$4,000. EPO fees are substantial and there
 588 are significant maintenance ~~costs~~ each year.

589 Technical translation costs are expensive. The major cost
 590 of filing a Japanese patent application is the cost of translat-
 591 ing the application into Japanese.

592 In ball park terms, it should be possible to file a provi-
 593 sional patent application for a healthcare invention for
 594 \$2,000–\$7,000, depending how much additional work is put
 595 into converting a publication into a patent application.
 596 Converting this to a utility application will cost up to \$20,000.
 597 Prosecuting a typical application to issuance will typically
 598 cost a further \$20,000 over its life in the U.S. Filing a US

599 utility application as a PCT application will cost \$3,000–
 600 \$5,000 in filing fees. A modest suite of national phase filings
 601 – Japan, EPO, Canada and Australia – will cost \$25,000–
 602 \$30,000. The costs to obtain and issue a patent are relatively
 603 modest in Canada and Australia. They are substantially
 604 higher in the EPO and Japan, typically about the same as in
 605 the U.S. In addition, the official fees for maintaining both the
 606 pending patent applications and the issued patents in effect
 607 in these countries is quite expensive – typically from \$500–
 608 \$1,500 per year per country. Thus, a lot of thought needs to
 609 be given to foreign filings.

639 which companies are publishing in that space, attending the
 640 conferences and professional association meetings in that
 641 field, hiring his graduate students and post docs and so forth.

642 What the technology transfer office brings to the table is a
 643 business perspective on how to translate the invention into
 644 products, sources of information and experience in valuing
 645 the technology and in negotiating with companies. And of
 646 course the funds to pay for the patent application process.

610 **54.11 Licensing The Patent**

611 Getting a patent is relatively straightforward – have an origi-
 612 nal, creative idea, pay your attorney, and you will get a pat-
 613 ent. However, the only reason for an academic scientist or
 614 physician to get a patent is to use it to induce a company to
 615 make the necessary commitment of human and financial
 616 resources to develop the invention and bring it to the market,
 617 and this is a lot more difficult. Anecdotally, one hears it said
 618 that fewer than 5% of patents are actually practiced though
 619 the data to support this is hard to come by.

620 Just as with prosecuting the patent, it is critical – in fact
 621 even more critical – that the inventor be very involved in the
 622 process. In a long term study [12] of 1,140 licenses com-
 623 pleted by six institutions – the University of Florida;
 624 Massachusetts Institute of Technology; Oak Ridge National
 625 Laboratory; Oregon Health Sciences University; Tulane
 626 University; and the University of Utah – the authors con-
 627 firmed the results of a preliminary study that had been car-
 628 ried out at MIT that the bulk of the leads that lead to completed
 629 licenses come from faculty (Table 54.4).

630 This may lead the inventor to ask: “If I made the invention
 631 and I find the licensee, what do I need these guys for, and in
 632 particular, why on earth are they going to get 70% of the
 633 money the technology brings in?”

634 The reason why the inventor is the source for over half the
 635 leads is quite simply that the inventor lives, eats, and breathes
 636 the science underlying the technology, while the technology
 637 transfer office has to work with the technologies of every pro-
 638 fessor and physician at the university. The inventor will know

647 **54.11.1 Types of Licensee**

648 Universities classify the companies that license their inven-
 649 tions into three categories:

- 650 • Large companies
- 651 • Small companies
- 652 • Start-up companies

653 In this scheme, a start-up company is one that is formed
 654 specifically to develop the technology. Small companies are
 655 those with fewer than 500 companies, which makes them
 656 eligible for various forms of government support, such as
 657 reduced fees at the patent office, access to the facilities of the
 658 Small Business Administration and eligibility for Small
 659 Business Innovation Research (SBIR) and Small Business
 660 Technology Transfer (STTR) grants.

661 In general, academic technologies tend to be so early
 662 stage, uncertain and with such a low probability of leading to
 663 a successful product that large companies find it hard to make
 664 the sorts of commitments that universities require from
 665 licensees, so the majority of academic licenses are with small
 666 companies, and only a third or so are with large companies.
 667 Table 54.5 shows the data for 2006 [13]:

668 This distribution between the types of licensee companies
 669 has held fairly constant for approaching 20 years.

670 Clearly, starting a new company is an important pathway
 671 for commercializing academic technology and we will consider
 672 this in some detail later in the chapter.

673 **54.11.2 Finding a Licensee**

674 Universities usually use a combination of passive and active
 675 marketing to find potential licensees.

t4.1 **Table 54.4** Sources of leads that lead to signed
 t4.2 license agreements at six institutions

t4.3 Source	t4.3 %
t4.4 Inventor	t4.4 56%
t4.5 Marketing efforts of OTT	t4.5 19%
t4.6 Company called university	t4.6 10%
t4.7 Research sponsor requested license	t4.7 7%
t4.8 Unknown	t4.8 7%

t5.1 **Table 54.5** Licensees of US academic inventions in 2006

t5.2 Type of company	t5.2 Number	t5.2 %
t5.3 Large companies	t5.3 1,648	t5.3 34.1%
t5.4 Small companies	t5.4 2,416	t5.4 50.0%
t5.5 Start-up companies	t5.5 764	t5.5 15.8%
t5.6 Total	t5.6 4,828	t5.6

676 **54.11.2.1 Passive Marketing**

677 Passive marketing is usually achieved through having a
 678 searchable website where a non-confidential description of
 679 the technology is posted. This website is usually reached
 680 through the technology transfer office's section of the uni-
 681 versity's website. It is still laborious for prospective licens-
 682 ees to search each universities website in turn, so there are a
 683 number of websites that accumulate technologies from a
 684 number of sources. Some of these are commercial – e.g.,
 685 Yet2.com [14] and UTEK [15] – though this has turned out
 686 to be a difficult business model to generate a return on capital
 687 (at the height of the dot.com boom there were over 40 tech-
 688 nology matchmaking sites). Others are not-for-profit. The
 689 pioneer was created by the Massachusetts Association of
 690 Technology Transfer Offices and the Massachusetts
 691 Technology Transfer Center and provides access to technol-
 692 ogies from all the universities, teaching hospitals and research
 693 institutes in Massachusetts [16]. The states of Florida and
 694 Texas have implemented similar systems. The Kauffman
 695 Foundation has supported another not-for-profit, iBridge, to
 696 create another website that appears set to become the domi-
 697 nant standard [17].

698 An important component of passive marketing is a one or
 699 two page (no more) non-confidential description (“NCD”) of
 700 the technology that can be freely distributed to “sell” the
 701 technology. This document should focus on the advantages
 702 of the technology and the benefits it can bring to the users of
 703 it, not on the technical features, and should summarize all the
 704 work that has been done to demonstrate that the invention
 705 works – animal data, prototypes, etc.

706 Another powerful passive marketing tool is the press.
 707 Issuing a press release to coincide with the publication of a
 708 key paper in a respected journal, or receipt of an important
 709 grant can generate coverage in the business press that can
 710 reach the attention of prospective licensees.

711 Active marketing involves directly approaching compa-
 712 nies with interests in the area. The normal course of events
 713 would be to identify a contact, either technical or in business
 714 development and establish contact by phone or email and
 715 send them the NCD. Another highly effective active market-
 716 ing approach is for the inventor to give talks at professional
 717 association meetings. There are also companies which
 718 organize small, expensive conferences on areas of science
 719 that are “hot” areas of innovation. Attendance is free for
 720 speakers.

721 **54.11.2.2 Reeling the Prospect In**

722 Once a company has been identified which is interested in
 723 the technology, the next step may be to send them the patent
 724 application. The next step will usually be a technical meeting

conducted under a confidentiality agreement. This may lead
 to the company doing some work to replicate the scientific
 conclusions, perhaps using samples provided by the inventor
 under a Material Transfer Agreement. The step after that will
 be to send the company a term sheet, a high level, 4 or 5 page
 documents that summarizes the key aspects of the agree-
 ment. If the parties can reach an agreement on a term sheet,
 the next step will be negotiation of a license agreement and
 perhaps sponsored research agreement.

The entire process can take from 3 to 12 months from
 initial contact to signed agreement.

54.11.2.3 Deal Structure

There are three important aspects of license agreements:

- the due diligence commitments of resources and/or prog-
 ress milestones that the licensee will agree to in order to
 successfully bring the technology to the market;
- the business arrangements by which the university will
 share in the financial success of the product; and
- the contractual terms that will govern the relationship,
 assign risk and management responsibilities.

The term sheet will handle the first two of these in some
 detail, but will only summarize the contractual aspects.

Due Dilligence

Due diligence commitments are both general and specific.
 General legal standards include:

“Best Efforts”, which means that the company will work
 harder on this project than any other. Companies will rarely
 agree to this standard.

“Commercially Reasonable Efforts”, which means that
 the company will work as hard on this project as it will on its
 internal projects of comparable market potential. This is the
 normal standard agreed to.

Specific commitments tend to fall into two categories –
 resource commitments or effort and achievements or outputs.

Resource commitments could include an agreement to
 spend specific amounts per year for a specified number of
 years, or to commit to devote so many FTE's to the project or
 to carry out specific experiments.

Achievement commitments are usually tied to preclinical
 and clinical development stages – prototyping of diagnostics
 and devices and selection and preclinical testing (tox, ADME)
 of lead compounds, followed by entering successive stages of
 clinical testing and submission for regulatory approval.

To prepare for either resource or achievement due diligence
 negotiations, the inventor should prepare what (s)he believes
 is a reasonable development plan, estimate the resources

771 needed and the likely timeline, and be prepared to discuss
 772 these with the company. It is critically important that there be
 773 well defined milestones every six to twelve months, particu-
 774 larly in the first two or three years, so that if the company
 775 reduces the priority of the project in this time frame, the uni-
 776 versity will be able to detect this, terminate the license and find
 777 a new licensee.

778 **Business Arrangements**

779 The business arrangements will be divided into a number of
 780 places in the license agreement. Some will pertain to reim-
 781 burasing expenses – patent expenses both past and future and
 782 the costs of any technical assistance the licensee will want
 783 the university to provide – some to payments to be made
 784 while the product is in development and some to payments to
 785 be made after the product has reached the market.

786 As a general proposition, academic inventions are gener-
 787 ally licensed at a very early stage, when the probability of
 788 successful product introduction is relatively low. The value of
 789 the technology at that stage is therefore relatively low, but
 790 will rise as the product moves through the development pro-
 791 cess. A lot of the negotiations will be devoted to agreeing how
 792 much the value has increased by what stage and how much of
 793 that increase in value should be shared with the university.

794 Another critical part of the negotiations will focus on the
 795 expected commercial pathway the licensee will follow – spe-
 796 cifically, whether the initial licensee will be the one that takes
 797 the product to market or whether they will develop the prod-
 798 uct a certain distance down the developmental pathway and
 799 then sublicense the product to a larger company which will
 800 actually take it to market. This decision has enormous com-
 801 mercial implications.

802 **Specific Business Terms**

803 *Patent Expenses*

804 The university normally will expect to see all its patent costs
 805 reimbursed at the closing of the deal and for future expenses
 806 to be reimbursed within 30 days.

807 *Upfront Fee*

808 The university will expect to receive an upfront fee to reflect
 809 the initial value of the technology. This will likely be between
 810 \$10,000 and \$1 million.

811 *Annual Minimum Royalties*

812 Annual Minimum Royalties (“AMR”) are royalty payments
 813 that are made whether the product is on sale and paying

earned royalties or not. They generally start at a relatively
 modest level of \$10,000 or 20,000 per year (and may not
 even start for 2 or 3 years after the license is signed) and then
 escalate over a 5 year period to around \$100,000. AMR’s are
 generally payable on January 1 of each year and are credit-
 able against earned royalties, milestone payments etc. due in
 the remainder of the year.

As well as guaranteeing a minimum level of income,
 AMR’s serve as a due diligence mechanism – if the company
 has stopped developing a technology, then the company will
 generally terminate the license rather than making the AMR
 payment.

Milestone Payments

These are payments made to reflect the achievement of points
 where the technology has increased in value. These are fre-
 quently the same as some or all of the due diligence mile-
 stones, but there may be additional ones such as patent
 issuance, achieving certain levels of sales volume etc.

Milestone payments for starting clinical testing are gener-
 ally fairly modest, but product approval milestone payments
 should be around \$1 million for a device and upward of \$5
 million for a drug.

Sublicense Income Sharing

If the initial licensee is a small company, then they may well
 not have the resources, both financial and sales and market-
 ing, to take the product all the way to regulatory approval and
 into the market. The license agreement should anticipate that
 the company will be sublicensing rights to a larger company,
 and should provide for the university to receive a percentage
 of all payments the licensee receives from the sublicensee.
 This percentage should be in the range of 15–25%, with
 higher rates due for payments received if the sublicense is
 issued closer to the date of the original license, and lower
 rates if the licensee spends a longer period of development
 and more of its own funds to get the technology to the point,
 where a large company is ready to take it over.

One of the difficult issues is the way the university will
 share in the sublicensee’s sales of products. Say the license
 provides for the licensee to pay a 5% royalty on its own sales
 of the product. Will the licensee agree that the university will
 receive 5% of the sublicensee’s sales? The answer is proba-
 bly “No” because at the time the license is signed, the licensee
 will have no idea of what royalty rate they will receive from
 their sublicensees. If the licensee can only negotiate an 8%
 royalty on the sublicensee’s sales and has agreed to pay the
 university 5% of the sublicensee’s sales, then they will only
 be left with 3% to compensate them for all the time and
 money they put into the development of the technology.
 Therefore, the licensee will normally agree to pay the university
 a percentage of the royalties they receive from the sublicensee,

perhaps the same percentage as they agree to pay of lump sums they receive from the sublicensee.

We have recently observed that if the agreed royalty rate is 3% or less, then it is generally possible to get the licensee to agree to pay that royalty rate on sublicensee sales too.

On the other hand, if the licensee is a large company, the agreement will probably provide for the university to receive the same set of payments and royalties whether the licensee sublicenses the technology to another company or takes it to market itself, and for the university not to share in any payments the company receives from sublicensing.

Royalties

Royalties are the payments the university will receive on the basis of the sales of the product. In general, royalty payments will provide the greatest economic return to the university if its technology does reach the market.

Royalties should be expressed as a percentage of sales, rather than say profits since sales is a very easy number for an auditor to verify when the university subsequently audits the licensee to ensure that the university is being paid all that it is entitled to receive.

One of the fundamental concepts of licensing is that the licensor should receive 25% and the licensee 75% of the pre-tax profits generated by a licensed product. This principle is known as the Goldscheider Principle or the 25% Rule, after Robert Goldscheider who first enunciated it. Goldscheider recently wrote an excellent review of the history, evolution and application of the rule [18]. The rule is a guide and provides only a starting point only and many other considerations must be taken into account in applying it, but the clear implication is that the more profitable the product, the higher the royalty rate. So, for instance, if the licensee suggests that as sales increase the royalty rate should go down (the implication being that you've made so much money already, the rate should go down), the counter would be that since products, particularly pharmaceuticals, get more profitable as sales increase, the royalty should actually be higher at higher annual sales levels, not lower.

Another issue that comes up with royalties is royalties that have to be paid to others. The licensee will generally ask to be allowed to offset some or all of royalties that have to be paid to third parties. If you are negotiating a relatively high royalty rate – say 6 to 10% – this will probably be a legitimate request. However, the licensee should only be allowed to deduct 50% of the third party royalties so that they have a strong incentive to negotiate low third party royalties. If you are negotiating a relatively low royalty rate – say below 5% and certainly below 3% – you should reject the request. The risk of a licensee having to license a third party patent that they didn't know about at the time of the negotiation has been substantially reduced since 2001 when US patent applications started being published (as noted above, previously

they were confidential till issued). It is legitimate therefore to ask a licensee to show you the third party IP they think they will need to license in order to practice the IP they're licensing form you.

Auditing: The Ronald Reagan Principle

Ronald Reagan once famously said "Trust – but verify". This is very true of license agreements. The only knowledge that the licensor has of what the licensee is doing is what the licensee chooses to tell the licensor. After product sales start, the licensee sends the licensor a quarterly statement that says "Here's what I've sold and here's what I owe you." It is essential that the licensor have the ability to verify what the licensee is telling them. This is achieved through an audit provision.

The licensor will generally have negotiated the right to send an independent CPA into the licensor's business offices once a year, with suitable notice, with the right to examine the licensee's business records for the prior three years (which is the length of time the IRS requires companies to keep records). Audit clauses in licenses generally require the licensor to pay the costs of the audit, which will generally be around \$30,000–\$40,000, unless the auditor discovers a shortfall in any payment of 5% or more, in which case the licensee has to pay the cost of the audit. Most red blooded auditors will be confident of their ability to find such a discrepancy, and studies have shown that audits generally do find shortfalls.

It is therefore generally a prudent policy to audit licensees every three years when annual royalties reach \$1 million and annually when they reach \$5 million.

54.12 Forming a Start-Up Company

Forming a start-up company is a particularly hallowed vehicle for technology transfer. As noted earlier, a dedicated start-up is the chosen commercialization pathway for about 15% of academic technology transfer transactions. It has considerable potential for creating substantial wealth for the inventor and the university. That said however, forming a start-up is not a pathway that should be pursued lightly or without a deep appreciation of the effort and commitment that will be required of the inventor.

54.12.1 Finding a Business Partner

The first requirement for a professor who wants to form a start-up (beyond an invention that is sufficiently disruptive to attract the investment needed to successfully commercialize the invention) is going to be a business partner.

960 How to find such a brave soul? There turn out to be a sur-
 961 prisingly large number of sources in the communities in
 962 which most academic medical centers are located. Some uni-
 963 versities can supply this capability through a group whose
 964 job it is to help faculty start companies. If the university does
 965 not directly provide this assistance, the Office of Technology
 966 Transfer may know individuals who are suitably experienced
 967 and who are looking for their next “gig.”

968 Professional advisors whom the Office of Technology
 969 Transfer uses, particularly lawyers, frequently have good
 970 contacts with the entrepreneurial community and will know
 971 suitable individuals. The alumni or development office may
 972 be able to introduce the inventor to an alumnus or alumna
 973 who is involved in the industry. The university’s Business
 974 School may have professors or alumni who have suitable
 975 industrial contacts. Other sources may be people the inventor
 976 has met through prior consulting relationships – say a VP of
 977 Business Development of a biotechnology company which
 978 has licensed one of their earlier inventions and who wants to
 979 start their own company. Other sources may be people to
 980 whom the inventor is referred by colleagues who have been
 981 down this path before. Some states have biotechnology cen-
 982 ters with an economic development mandate that can provide
 983 contacts or provide direct assistance (e.g. Ohio’s Thomas
 984 Edison Program [19]; Pennsylvania’s Ben Franklin Program
 985 [20]; New York’s Center of Excellence Program [21].

986 Many states have biotechnology associations that are nat-
 987 ural congregating points for biotechnology entrepreneurs.

988 It is critical that the business partner has credibility in
 989 the life sciences start-up community. Resist the temptation
 990 to team up with say a stock broker or real estate executive
 991 or business lawyer (all of whom the author has seen inven-
 992 tors team up with, generally with frustrating and unsatis-
 993 factory results) because they have more with familiarity
 994 business than the professor does. They will be a negative as
 995 you move down the road and will probably quickly lead
 996 you astray.

997 **54.12.2 Working with Students**

998 Before sitting down with a potential business partner, the
 999 inventor needs to have captured the vision he has for the
 1000 company. This presents a chicken and egg situation – you
 1001 need the commercial vision to engage a business partner, yet
 1002 you need the business partner to develop the commercial
 1003 vision. One way of cracking this egg is to see if your busi-
 1004 ness school (or a nearby business school if you are at a hos-
 1005 pital or practice that’s not part of a university) has courses
 1006 that require the students to write a business plan or develop a
 1007 business strategy or do a market research study. The profes-
 1008 sors who run these courses always have a need for business

and product ideas for the students to work on, so finding and
 making contact with such professors may be productive.
 You’ll need to keep the academic calendar in mind – most
 likely there will only two starting opportunities available –
 September and January, and the professor will want to have
 everything lined up at least a month, probably two, before
 the start of the semester. That said, the quality of work you
 can get from a dedicated inter-disciplinary team of students
 working for 14 weeks is stunning.

54.12.3 Communicating the Idea

Ultimately, you will need four documents to “sell” a company
 concept to all the stakeholders you’re going to need – employees,
 investors, landlord, customers, etc.

In order of difficulty, and effort to generate them, these
 four documents are:

- An Elevator Pitch 1024
- A PowerPoint presentation 1025
- An Executive Summary 1026
- A full Business Plan. 1027

54.12.3.1 Elevator Pitch

The elevator pitch is a two minute summary of the opportunity
 – what you are doing, the scale of the opportunity, what’s
 unique about your approach to solving the problem, how you
 will going to change the world and how the person will profit
 enormously by joining you on the adventure. The term comes
 from the idea that you get on an elevator and suddenly realize
 that your fellow passenger is an ideal potential investor/
 employee/customer/whatever and that you have them captive
 for the duration of a 60 floor elevator ride.

The inventor should have an elevator pitch integrated into
 their psyche and be ready to launch into it at a moment’s
 notice, tailoring it to the specific audience – potential investor/
 employee/board member/customer, etc. A good elevator
 pitch takes a lot of practice. It’s very easy to go into too much
 technical detail or to stay stuck on the product idea and the
 company concept and not get to asking your captive audience
 for what you think they can contribute and how they’ll profit
 from working with you.

If you can’t capture the idea in two minutes, you haven’t
 thought about it sufficiently. To be able to bring together
 all the resources you need, you have to be able to boil the
 opportunity to a simple, attractive summary that can be com-
 municated in two minutes.

Some people advocate practicing at the mirror or giving
 the pitch to your dog. As the last step before going “live,”
 you should give it to your mother and see if she “gets it”.

1055 The sole purpose of the elevator pitch is to get the person
 1056 you're giving it to that they want to hear more and will agree
 1057 to meet with you later to learn more.

1058 **54.12.3.2 The PowerPoint Presentation**

1059 If you get that next meeting, you'll need a PowerPoint pre-
 1060 sentation, which is the heart and soul of communicating a
 1061 new company concept. Like an elevator pitch, it must flow
 1062 seamlessly and communicate the opportunity, the company's
 1063 approach to filling the need, the status of the technology,
 1064 what's unique about the company's approach, including the
 1065 management team and the intellectual property position that
 1066 will keep the enemy at bay, the company's financial projec-
 1067 tions, the investment the company is looking for and how the
 1068 investors will make money – the “exit”.

1069 The individual slides of the presentation should be attrac-
 1070 tively designed, not cluttered with too many words and should
 1071 use visuals where ever possible – a picture is worth a thousand
 1072 words, and a video's worth ten thousand. A good presenter
 1073 will take one and a half or 2 min per slide, so a presentation for
 1074 a 1 h meeting – 40 min plus 20 min Q&A – should be 20 to 25
 1075 slides, ~~no more~~. Use a large “clean” sans serif font like Arial
 1076 rather than say Times Roman. Always try giving the slide
 1077 show using an LCD projector in a sunny room before the first
 1078 meeting – slides that look great on a computer screen can have
 1079 insufficient color contrast and be difficult to read under “real
 1080 world” conditions. Take and use your own laptop rather than
 1081 downloading via a flash drive to their computer – that way you
 1082 know you'll have compatible software versions, have all the
 1083 plug-ins you'll need – particularly important if you're using
 1084 video. Take a laser pointer with you to emphasize the talk.

1085 In short, look technically competent, professional, orga-
 1086 nized and in control when you give a presentation on your
 1087 company.

1088 **54.12.3.3 The Executive Summary**

1089 The executive summary is a five to ten page summary of the
 1090 company's business plan that summarizes the presentation.
 1091 If the audience liked the PowerPoint presentation, they'll ask
 1092 for an executive summary and a copy of the PowerPoint to
 1093 share with people within their firm that they want to get
 1094 excited about the opportunity. It is probably the longest writ-
 1095 ten description of the company that people will ever read.

1096 **54.12.3.4 Business Plan**

1097 The company must always have a Business Plan, which is a
 1098 complete description of where the company is, where it's

going and what it needs to get there. It documents the scale
 of the market and the opportunity, and demonstrates the
 company's ability to meet the need. It analyses the planned
 pricing of the product. It describes and justifies the viability of
 the company's business model – how the company will gen-
 erate revenues. It describes the management team and how
 that will evolve. It identifies the partnerships with other com-
 panies that the company will need to get to the market. It looks
 at potential competition and how the company's intellectual
 property position will keep competition at bay. It contains
 detailed financial projections – development costs, capital
 needs, operating costs, profitability and financial return.

A company's business plan is constantly evolving. At a
 minimum, it should be reviewed every three of four months
 in the light of changing market circumstances and the com-
 pany's progress. The initiation of a round of fund raising will
 normally trigger a new edition of the business plan.

Few outside the company will ever read the business plan
 cover-to-cover. However, your ability to answer detailed
 questions that come up in your presentations will critically
 depend on the thoroughness of the thought and analysis that
 went into the preparation of the business plan. You write it
 for yourself not for others.

54.12.4 Forming the Company

You can (and should) test the waters for your company con-
 cept without actually incorporating. You can project a very
 professional image for the company with do-it-yourself com-
 puter graphics without actually incorporating. Nobody will
 check at this stage. The story of how Larry Page and Sergei
 Brin raised the seed round financing for Google is a Silicon
 Valley legend. They were introduced to Andy Bechtolstein,
 the Co-Founder and Chairman of SUN Microsystems and a
 fellow Stanford alumnus. He liked the story, went out to his
 Ferrari, got his checkbook and wrote a check for \$100,000.
 Brin and Page had to quickly incorporate the company in
 order to be able to open a bank account to cash the check.

You should check out that the company's name has not
 been taken by another company in the same technical area
 as yourself, together with a suitable URL. It may be worth
 paying the modest fee to reserve the URL at this stage.

However, if you start to get the sense that the company is
 going to be investable and so may be viable, then you will
 want to move ahead and incorporate. Although there are an
 enormous number of web sites that will offer to incorporate
 a company for you for as little as \$99, you should use the
 services of a major law firm. Particularly in the major inno-
 vation hubs, the large law firms understand that mighty oaks
 from tiny acorns do indeed grow and that their future major
 clients start out as impoverished start-ups. Many of these law

1148 firms have fee deferral programs under which, for a small
 1149 retainer, they will accumulate the fees incurred by the com-
 1150 pany until some significant funding threshold is reached, at
 1151 which point the accumulated fees become due.

1152 It will ultimately be to the company's considerable advan-
 1153 tage to be seen to be using the services of a top tier law firm.
 1154 They will have expertise, experience and contacts to contrib-
 1155 ute as well, and the quality of your advisors does speak
 1156 legions for you.

1157 They will also prevent you from making the Number One
 1158 mistake of start-ups, which normally occurs at this point –
 1159 giving out Founders' stock to the Founders without an earn
 1160 in. Since start-ups are generally planned by people who are
 1161 still working for someone else, or are looking at multiple
 1162 opportunities, it is quite likely that one or more members of
 1163 the Founding team at the "virtual" stage will decide not to
 1164 join the company, or may quickly move on. It is critical that
 1165 the same amount of the company's stock not be held by peo-
 1166 ple who aren't fully committed to the company as by those
 1167 who have staked their future financial well being on the com-
 1168 pany's success. Therefore, it is a standard practice to make
 1169 people earn-in their stock over 4 or 5 years. If they leave
 1170 sooner than this, whether of their own volition of at the com-
 1171 pany's request, they forfeit the balance. This keeps them
 1172 motivated, preserves fairness and prevents unnecessary dilu-
 1173 tion of the company's stock.

1174 A good law firm start-up package will include things like
 1175 employment contracts, confidentiality agreements, consulting
 1176 agreements, board meeting minutes and corporate resolutions,
 1177 in addition to the standard Certificate of Incorporation,
 1178 By-Laws and Shareholders agreements and share certificates.

1179 **54.12.5 The Initial Funding**

1180 The Founders will normally buy their stock in the company
 1181 at "Par Value", a purely nominal value that is printed on the
 1182 share certificates and is typically 1¢ or oven 0.1¢ per share.
 1183 So, if they decide to issue themselves 5,000,000 shares, they
 1184 will contribute \$5,000 at 0.1¢/share or \$50,000 at 1¢/share,
 1185 enough to pay the legal costs of incorporation, but no more.

1186 The first "real" money that goes into the company and
 1187 that will be used to start its operations can come from any
 1188 one of a number of sources:

- 1189 • Second mortgage/credit cards
- 1190 • Bootstrapping – selling products and services
- 1191 • Friends and family
- 1192 • Angels or Angel Groups
- 1193 • SBIR/STTR grants
- 1194 • Corporate partnerships
- 1195 • Venture capital

Table 54.6 Initial sources of funding for university spin-outs, FY 2004

	Number	%	
<i>Individuals</i>		49.34%	16.1
Friends and family	94	20.52%	16.2
No external funding	57	12.45%	16.3
Individual angel(s)	49	10.70%	16.4
Angel network	26	5.68%	16.5
<i>Institutional sources</i>		44.54%	16.6
Venture capital	85	18.56%	16.7
State funding	36	7.86%	16.8
SBIR/STTR	32	6.99%	16.9
Corporate partner	25	5.46%	16.10
Institutional funding	26	5.68%	16.11
<i>Other</i>	28	6.10%	16.12
<i>Total</i>	458	100.00%	16.13

In 2004, the AUTM Survey asked respondents what the
 initial sources of funding for their spin-out companies were.
 The results are shown in Table 54.6.

It is clear that university spin-outs more frequently attract
 their initial funding from individuals than from institutional
 sources.

A more detailed source of these funding sources follows.

54.12.5.1 Second Mortgage/Credit Cards

This is a classical method of starting a company, but probably
 doesn't have much relevance to a life sciences startup because
 of the total financing needs the company will have.

54.12.5.2 Bootstrapping

This is when a company has early sales opportunities – say
 selling reagents to the research market – and can use the
 revenues to fund developing its main products. Bootstrapping
 can reduce capital needs, but will rarely totally eliminate the
 need for investment sources.

54.12.5.3 Friends and Family

Also known as "friends, family and fools", this approach
 involves passing the hat round the more affluent members of
 the inventor's family, social and even professional circles.
 This can raise a significant amount of money, but comes with
 strings. As several inventors have observed to the author:
 "It does make for some tense Thanksgiving dinners" when
 the company hits the inevitable patch of turbulence.

If the company plans on raising later rounds of financing
 from institutional sources, it may find that they won't want to
 have a large number of small shareholders, and it may be

1224 appropriate to have them invest by buying a membership
 1225 interest in an LLC company, so that there would be a single
 1226 voting entity representing all the investors in that round.

1227 **54.12.5.4 Angels or Angel Groups**

1228 Angel investors are rich individuals to whom the inventor is
 1229 not related and who invest some or all of their wealth in
 1230 young start-ups. They are generally people who have made
 1231 their money themselves entrepreneurially rather than having
 1232 inherited (when it is normally tied up in trusts and protected
 1233 by zealous and very conservative trust attorneys).

1234 Some Angel groups have a pooled fund and invest out of
 1235 that, while others operate as meeting conveners and bring a
 1236 number of Angels to a monthly breakfast or lunch meeting at
 1237 which companies make presentations, and each individual
 1238 investor decides if he/she wants to invest in a particular
 1239 opportunity and, if so, how much.

1240 The more highly developed a region is as an innovation
 1241 hub, the more likely it is that there will be organized Angel
 1242 groups operating. For instance, there are close to 20 organized
 1243 Angel groups operating in Massachusetts.

1244 **54.12.5.5 SBIR/STTR grants**

1245 The Small Business Innovative Research Program and the
 1246 Small Business Technology Transfer Research Programs [22]
 1247 have been mainstays of the US economy for 30 years since
 1248 the SBIR program was “test marketed” by the NSF starting in
 1249 1978 and expanded to all federal agencies in 1982.

1250 They are Federal grant programs and so are a particularly
 1251 attractive way to fund a company’s development since they
 1252 are nondilutive – the Government asks for nothing in return
 1253 other than a commitment by the company to commercialize
 1254 the research.

1255 Currently, all Federal agencies with an external research
 1256 budget of \$100 million or more have to dedicate 2.5% of
 1257 their budget for SBIR grants and 0.3% to STTR grants, so
 1258 over \$2.3 billion is available for these grants, a substantial
 1259 pool of nondilutive investment funds. There are three solici-
 1260 tations a year and proposals are solicited for specific fields
 1261 that the agency has established as a priority. The grant pro-
 1262 posals are of limited length.

1263 The Phase I awards are for \$100,000 for six months and
 1264 are intended to demonstrate feasibility of proof of principle.
 1265 Phase I recipients are eligible to submit Phase II proposals,
 1266 which are worth \$750,000 over two years and are intended to
 1267 carry out the project.

1268 The PI of an SBIR must be employed at least 51% by the
 1269 company at the time of the award (not the time of the submis-
 1270 sion, and the company must be able to demonstrate that it has

adequate facilities to carry out the research. A collaboration
 with a university is not required, but upto 30% of a Phase I
 award and 50% of a Phase II award can be subcontracted to
 a university.

A STTR is by contrast at an earlier stage. It requires a
 collaboration with a university. At least 30% and as much as
 60% of the work can be done at a university. The PI can be
 either at the university or at the small company.

54.12.5.6 Corporate Partnerships

It may be possible to fund the company’s start-up and early
 stage development through a partnership with a larger com-
 pany though it is highly likely that at the time the technology
 is transferred from the university, it will be at too early a
 stage and too low a probability of success to be attractive to a
 larger company and for this to be a viable approach. Corporate
 partnerships tend to be important later in the company’s
 development.

54.12.5.7 Venture Capital

Venture capital funds are pools of funds invested by university
 endowments, very rich individuals, insurance companies, pen-
 sion funds and so forth. These investors, who are known as
 Limited Partners, can afford to tie up their money for a long
 time in order to secure a superior rate of return. This is critical
 for venture capital funds because the fund will make invest-
 ments in early stage, privately held companies and will most
 likely not be able to sell the investment for many years.
 Therefore, the Limited Partners typically are asked to invest
 their funds for ten years with no right to ask to be repaid.

Some companies have their own venture capital funds,
 but these tend to be more fickle investors. They rely on the
 parent company to make new funds available each year, and
 corporate venture funds are frequently throttled back in times
 of economic downturn when the parent’s cash flow suffers.

The actual investments are made by General Partners.
 These are the people that the founders of the company will
 deal with. General Partners are generally people who have had
 a successful operating track record in large technology-based
 companies, or more likely in small venture-backed companies
 that the venture investors have made a lot of money in. A few
 grow from freshly minted Associates recruited fresh from their
 MBA’s into partners, and a very few service providers such as
 lawyers have become successful venture capitalists.

The General Partners will normally draw 2.5% of the funds
 under management each year to operate the partnership – pay
 the rent, salaries, travel, legal expenses etc. This means that
 over the ten year life of the fund, 25% of the invested funds
 will go to operate the fund, and only 75% will actually be

1318 invested in companies. In addition, when the fund makes a
 1319 profit on an investment, the limited partners will first have
 1320 their investment returned to them, and the General Partners
 1321 will receive 20% of the net profits from that investment.

1322 If a venture capital fund makes ten investments, it will
 1323 expect to write off four (i.e., lose its entire investment), make
 1324 a two or three times return on four, and a ten times or higher
 1325 return on the final two. If you run the numbers, allowing for
 1326 25% of the fund going for operating expenses, and the General
 1327 Partners getting 20% of the net profits on the successes, this
 1328 will result in a 25–30% annual return to the Limited Partners.
 1329 This will then allow the General Partners to go back to the
 1330 same Limited Partners when they are starting to raise their
 1331 next fund. Venture Capital is a very Darwinian business – their
 1332 first objective is to successfully reproduce themselves!


1333 The key conclusion from this analysis is that if you want
 1334 to attract venture capital investment, you must be able to
 1335 show that venture capitalist that if the company is a success,
 1336 they will make 10× their investment. If you think it will take
 1337 an investment of \$20 million to launch your products, then
 1338 you must be able to show the VC's that your company will be
 1339 worth \$200 million.

1340 As Table 54.6 shows, venture capital is the second largest
 1341 source of funding for university spin-outs, but is the initial
 1342 source of funding less than 20% of the time. Most technolo-
 1343 gies are simply too untested when they're transferred out of
 1344 the university to be ready for venture capital. This is particu-
 1345 larly true in the case of drugs. VC's are generally going to be
 1346 ready to invest in a new drug company only when the
 1347 company is a year away from starting human clinical trials,
 1348 and very few academic drug discoveries are that far along
 1349 when federal funding runs out. The entrepreneur's challenge
 1350 is going to be how to fund the gap between the expiration of
 1351 federal funding and when the company is ready for venture
 1352 capital. VC's are more likely to fund a start-up diagnostic or
 1353 medical device company.

1354 **54.12.5.8 Who Gets How Much: The Capitalization**
 1355 **("Cap") Table**

1356 There are normally two types of stock in a start-up company:
 1357 Common stock
 1358 Preferred Stock

1359 **Common Stock**

1360  *Common stock is generally a reward for effort or the provi-*
 1361 *sion of services in kind – the original "sweat equity". The*
 1362 *founders will receive common stock, as will the management*
 1363 *team for their future services and the university (whose*
 1364 *investment of intellectual property in the new venture repre-*
 1365 *sents past effort).*

Preferred Stock 1366

Preferred stock is normally reserved for investors who pay 1367
 cash for it. It's full name is generally Preferred, Redeemable, 1368
 Convertible Stock. 1369

Preferred means that the stock enjoys various preferences 1370
 over common stock. Redeemable means that the investors 1371
 can force the company to repay their investment under cer- 1372
 tain circumstances. 1373

Convertible means it's convertible into Common stock 1374
 under certain circumstances. The first round of investment 1375
 will normally be called the Series A preferred, the second 1376
 round of investment will be called the Series B Preferred, 1377
 etc. Each successive round normally takes priority over the 1378
 previous round if times get tough. (When time is good, 1379
 everybody does well!) 1380

Dividing Up the Founders Stock 1381

This will undoubtedly be the subject of intense debate 1382
 between the founders. One common philosophy is that the 1383
 two equal components of a start-up company are the technology 1384
 and the management team that's going to stake its financial 1385
 security on this new venture. The technology is equally 1386
 divided between the intellectual property, which the university 1387
 owns, and the know-how, which is in the inventor's head, and 1388
 which he can monetize by agreeing to consult exclusively for 1389
 the new venture. This philosophy would result in a Founders' 1390
 stock distribution of: 1391

- 25% to the inventor 1392
- 25% to the university 1393
- 50% to the management team 1394

Another philosophy has the university being another 1395
 founder alongside the founding management team. 1396

In yet another philosophy, the university will ask for a 1397
 relatively small stake – say 5% – but that they be protected 1398
 from dilution till a specified amount of investment capital 1399
 has been raised by the company – say \$5 million. 1400

It is critically important that the management team's stock 1401
 be earned in over typically four years. The management team 1402
 share should include adequate provision for the additional 1403
 employees who will need to be hired until the next financing. 1404

The Investor's Stake 1405

The investors will normally expect to get control of the com- 1406
 pany for their initial investment. The implication of this is 1407
 that the company should not sell itself too cheaply. If you're 1408
 going to have to give up half your company, then give it up 1409
 for \$5 million, not \$1 million. Go out with an ambitious tech- 1410
 nical plan that requires \$5 million to achieve. The VC's may 1411
 balk at investing \$5 million in an initial investment in a 1412

1413 totally untried management team, and one way to finesse
 1414 this calculation is to stage the release of the funds – say \$1
 1415 million initially, to get the company to a certain technical
 1416 achievement, with another \$2 million released when that
 1417 milestone is reached, and the final \$2 million released when
 1418 the company successfully achieves a second technical (or
 1419 business) milestone.

1420 **The Next Round**

1421 The number of shares in the company will normally be
 1422 adjusted (by splitting or reverse splitting) so that the price of
 1423 the Series A stock is \$1/share. If the company makes good
 1424 progress, the Series B will hopefully be sold at a higher per
 1425 share price – say \$2/share or \$3/share, perhaps even \$5/
 1426 share. This means that the company will give up less of itself
 1427 proportionately to raise the next round of financing, and the
 1428 value of the existing shareholders stake will grow, even
 1429 though they won't be able to sell their stake and it will be a
 1430 paper profit only.

1431 If the company doesn't do well, then the next round may
 1432 have to be sold at a lower per share price than the previous
 1433 round. That's when things start to get ugly, and is beyond the
 1434 scope of this chapter. Hopefully, it'll never happen to you.

1435 **What About the Seed Investors?**

1436 If the company raises a relatively small amount of money,
 1437 from friends and family or Angel investors, the investment
 1438 will probably be made not by a purchase of stock, but in the
 1439 form of a loan secured by a note which is convertible into
 1440 stock in the future. This has a number of advantages:

- 1441 • The legal costs are much lower
- 1442 • The value of the company can be set when a more substantial amount of money is raised from sophisticated investors a little later

1445 The seed round investors are generally rewarded for
 1446 investing early by converting their loan into stock at a lower
 1447 per share price than the Series A investors – say at a 20%
 1448 discount. So, if the Series A per share price is \$1/share, then
 1449 the seed round loan will be converted into stock at a price of
 1450 \$0.80/share, so they will receive 25% more share per dollar
 1451 invested as the Series A investors.

1452 **Subsequent Rounds**

1453 The prior arguments will apply to subsequent rounds of
 1454 financing, which will be labeled Series B, C, D, E etc. High
 1455 tech companies will generally be expected to raise only A, B
 1456 and C rounds and then to have achieved self sufficiency. Life

sciences companied may need additional rounds of financing. 1457
 Acusphere, an MIT spin-out developing in vivo diagnostics 1458
 for cardiovascular conditions, went as far as a Series J before 1459
 pulling off an IPO. Each round's investors will have priority 1460
 over those in the prior round. 1461

The Exit 1462

At this stage, the company is still privately held, and there is 1463
 no market for the stock. While the value of the company may 1464
 have increased substantially, this is still all on paper, and nei- 1465
 ther management nor investors can actually sell their stock 1466
 and realize any part of that value. 1467

At the end of the day, being able to realize the value that 1468
 has been created is what people will care about, and that is 1469
 achieved through an exit. 1470

There are only two possible exits that will put cash in 1471
 founders', managements' and investors' pockets: 1472

- 1473 • Acquisition, for cash or for stock in a publically traded 1474
 company, or
- 1475 • An Initial Public Offering ("IPO") through which the 1476
 company's shares are listed on a stock market, generally 1477
 the NASDAQ.

Another exit mechanism is acquisition by or merger with 1478
 another privately held company. This may help build value, 1479
 but it will still be "paper profits" until one of the prior two 1480
 events happens. 1481

The acquisition route may seem more attractive, but ven- 1482
 ture capital investment terms and conditions, specifically 1483
 "liquidation preferences" may skew distribution of the pro- 1484
 ceeds toward the investors and away from founders and 1485
 management. 1486

IPO's have become considerably more expensive and dif- 1487
 ficult to pull off since the passage of the Sarbanes–Oxley Act 1488
 in the wake of the Enron debacle. The benefit of an IPO is 1489
 that it allows for the stock price to increase after the IPO (and 1490
 equally to decrease!). The negative is that the shareholders 1491
 from the company's private days will be required to sign a 1492
 lock-up agreement, in which they agree not to sell their stock 1493
 for six months (12 months for European stock exchange 1494
 IPO's). Most new companies founded currently are founded 1495
 in the expectation that the exit will be by acquisition. 1496

54.13 Case Study 1497

54.13.1 CALM 1498

Institution: McGill Univ. *Location:* Québec, Canada *Field* 1499
of: Obstetrics 1500

1501 Emily Hamilton, M.D., a McGill University obstetrics
1502 and gynecology professor, was teaching at Montreal's Jewish
1503 General Hospital when it occurred to her that doctors and
1504 nurses could better evaluate the progress of delivery if they
1505 knew how their patients were compared with others.

1506 "Students were asking simple questions like, 'How do
1507 you know when labor is slow?'" Hamilton says. Doctors
1508 were relying on a small study of women conducted in the
1509 1950s for information about delivering babies, yet a num-
1510 ber of medical developments, such as epidurals, greatly
1511 influence the average length of labor. When Hamilton
1512 looked at the big picture, she saw that the power of comput-
1513 ing combined with large-scale studies could tell physicians
1514 and nurses what comprised a normal labor for different
1515 women.

1516 Her revelation occurred in the early 1990s, and today the
1517 Computer-Assisted Labor Monitoring, or CALM™, system
1518 is installed in numerous North American hospitals. Hamilton's
1519 studies show that the technology can reduce Cesarean sec-
1520 tions. Fewer Cesareans mean less pain and quicker recupera-
1521 tion for women and less time required by surgeons. The
1522 CALM system tells medical personnel when a labor that
1523 appears long may, in fact, be progressing normally. After
1524 inputting information about the patient, a simple-to-read
1525 graph appears on the screen. The graph shows three lines: the
1526 woman's progression of labor, and the high and low limits of
1527 statistically normal progression, based on data from other
1528 women with similar clinical characteristics. Doctors can
1529 quickly and easily update the touch-sensitive screen.

1530 In addition to her position on the McGill faculty, Hamilton
1531 now serves as vice president for medical research and scien-
1532 tific advisory board chair for LMS Medical Systems Ltd.,
1533 which distributes and monitors CALM in North American
1534 facilities. The company is based in Montreal, and Hamilton
1535 continues to hire engineering and computer science gradu-
1536 ates from McGill and Université de Montréal as the company
1537 expands. Read more at <http://www.lmsmedical.com>

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