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U.S./Canadian Licensing In 2003: Survey Results

BY RICHARD RAZGAITIS*

Initial Results of a Survey Conducted in January/February 2004 by the Licensing Foundation of LES (USA & Canada), on behalf of The Licensing Foundation.

ABSTRACT AND SUMMARY OF FINDINGS

The results are reported of a Web-based survey of licensing practices of LES (USA & Canada) members. Such survey was sponsored and conducted by the Licensing Foundation of LES (USA & Canada) (www.licensingfoundation.org). It was conducted in January and February of 2004 by contacting 5,349 member e-mail addresses and providing a link to the online survey.

The focus of the survey and the analysis of the results was on companies who are intellectual property owners and who engage in out-licensing despite their ability, in principle, to directly commercialize their IP or in in-licensing despite their general ability to develop their own technology through internal R&D. 229 respondents to this survey fit this profile. These were further separated into “large” and “small” using the demarcation of 1,000 employees.

The results reported here are related to the business process “trade,” or dealmaking, involving technology-based IP. Such dealmaking process was surveyed for three time periods: getting to the point of substantive negotiations, consummating such negotiations, and living with the deal done.

From these data it appears that only a small portion of what is believed to be licensable IP actually is licensed within the time frame of a respondent’s experience. A substantial number of factors contribute to deal breakdown both during the period when potential licensees are identified as well as during substantive negotiations, and it is not always about “the money.” Finally, looking back on deals done within the past year, the survey suggests that a substantial number of such agreements would have been done differently with respect to various deal terms used in the agreement.

INTRODUCTION

“Licensing” is, literally, the first word of LES, and the single-word appellation of the business process that best describes our Society’s primary interest and what most of us designate as our profession (industry) and craft (technê). Yet, the industry of licensing, unlike almost every other business, is both difficult to define or encompass.

A legal perspective of licensing focuses on the forms and protections of intellectual property (IP) rights, contractual vehicles by which such rights can be conveyed, and the applicability of governing law to the behaviors and misbehaviors of individuals and legal entities. A financial perspective leads to an analysis of the value of IP rights as they may be packaged in various forms and with other assets so they may be subjects of commercial transactions (“licensees”). The perspective of a business owner or manager views licensing, and IP, as mechanisms by which investments made can be realized, or the investments of others acquired, all as part of the competitive context of successfully satisfying the needs of its customers, present and future. The licensing expanse, almost like the heavens themselves, seems to cover an earthful (and earful) of activities and interests:

• Internal Research & Development (IR&D), contract R&D,
• Entrepreneurship, innovation, inventions, discoveries, creations,
• Patents, trade secrets, copyrights, trademarks,
• Valuation, pricing, royalties, equity/warrants, minimums, changes of IP rights, supply/purchase commitments,
• Agreements (deals), deal-marketing, negotiation, dealmaking,
• Spinouts, Joint Ventures/Partnerships, research collaborations, startups/NEWCOs, M&As (Mergers & Acquisitions),
• Infringement/IP-theft litigation/negotiation/settlement,
• Government policy related to IP law and policy, economic development, and trade.

1. www.licensingfoundation.org. The Licensing Foundation is a wholly-owned 501c3 subsidiary of LES (USA & Canada).
2. The Licensing Foundation in January 2004 was managed by its Board comprised of Louis Berneman, Todd Dickinson, Mel Jager (President), Dwight Olson, Richard Razgaitis, Art Rose, and Jim Soberaj, on behalf of the Board of LES (USA & Canada).
3. Some have characterized the licensing “industry” as the “market for knowledge.” The classical Greek term technê, commonly translated craft or art, and perhaps in our context and times could be best translated as “know how,” is more appropriate than “knowledge.” Although we use “licensing industry” as subject of study, it could perhaps be more comprehensively defined as the “market for owned/protected technê.”

*Richard Razgaitis, President of the Licensing Foundation (2004/5).
funding and the resulting invention disclosures and patents but also data on license agreements entered into and royalties and other IP payments received.7 For many years Battelle has performed annual surveys to provide forecasts of annual R&D spending in both industry and government.8

In 2003 LES reported on the results of a survey of compensation for licensing professionals.9 Other LES groups, such as its Intellectual Capital Management Committee have conducted surveys of licensing metrics relating to best practices. “An International Survey on Technology Licensing Practices” has been completed in draft form on behalf of LES International (LESI), LES (USA & Canada), and LES France.10 This as yet unpublished survey analyzes 160 written questionnaires regarding 297 technology licensing agreements primarily in Europe, Japan, U.S.A., and Canada. Other such licensing process/ issues surveys done by LES members (and others) include Degnan,11 McGavock,12 McGavock,13 and the Corporate Legal Times.14

Royalty rate and other IP payments have been widely surveyed by many. Public filings of license agreements that represent material transactions have been useful source data for IP payments and in certain respects for deal structures, particularly in the healthcare industry (pharmaceuticals and biotechnology) and have been compiled into databases by commercial vendors.15 Razgaitis has summarized numerous such royalty rates and other financial surveys, some dating back to 1975.16

Except for the AUTM and Battelle surveys, and the U.S. Patent Office statistics, most of the other survey information has been ad hoc and reflects the particular interests of the surveying group.

One core measure of an industry’s significance is total annual revenue for all segments by all participants, and an understanding of such industry’s structural taxonomy. There have been multiple sources who have claimed that in the U.S., the licensing industry has $100 billion annual “royalty licensing revenues,” which appears to include all forms of IP patents including running royalties;17 however, there does not appear to be a research foundation for this (or any other) estimate. If such revenues are indeed expressed in nine-figures (> $100 billion).

4. Note that the terms “license” or “licensing” do not explicitly appear in any of such bulleted list, although licensing is commonly an important, directly-related business practice.
5. [Internet]. Available from: http://www.uspto.gov/web/offices/ac/ido/oeip/taf/reports.html#by_list
6. U.S. software only revenues (which arguably could be considered as substantially all licensing revenue) in 2001 are estimated to be $69 billion with an additional $100 billion in sales outside the U.S.; Service Annual Survey, http://www.census.gov/ret machining/annres/annres511.pdf
17. Such statistic has been cited for “retail” licensing (primarily trademark licensing): “Licensing is a $100 billion retail market worldwide, with $70 billion in business in North America alone, says Murray Altchuler, executive director of the International Licensing Industry Merchandisers’ Association (LIMA).” [Citation at: http://www.entrepreneur.com/article/0,4621,226781,00.html]. And $100 billion/year is also cited for technology licensing revenues: “The IP licensing market has grown an estimated 700 percent, from $15 billion in 1990 to well over $100 billion in 1998. Patent licensing revenue is predicted to top half a trillion dollars annually by 2005.” [Citation at: “The Basics of Financing Intellectual Property Royalties, Part III: What is the Market?,” by Licent Capital, July 2, 2001, http://www.cafezine.com/index_article.asp?id=4126&deptId=3]
of corporations, then licensing would indeed represent a major industry joining other nine-figure segments such as computers/electronic products ($350 billion),

19. telecom ($425 billion),

18. pharmaceuticals, and R&D itself ($284 billion).

In this context, the Licensing Foundation commissioned an initial survey of licensing activity in U.S. for the purpose of contributing to the above available information resources but also, perhaps, to inaugurate a regular, systemic investigation to complement and expand the understanding of licensing as an industry and as business practices. The long-term aspiration of such surveying initiative was and remains:

*Provide an annual, synoptic perspective on key statistics, events, and trends in the world of “Licensing” that can assist licensing professionals in understanding and advancing the business environment in which they operate and to which they contribute, and can be used by the public, academic researchers, and government policy analysts to grasp the issues and impacts of licensing business practices.*

Based on this background and long-term objective, the Foundation prepared a Request for Proposal (RFP) which was sent to some 30 organizations including leading MBA and entrepreneurship academic programs and other entities known for their interest in this or related areas. After a review of several proposals that responded to the RFP, the team of Professors, Iain Cockburn of Boston University and Ajay Agrawal of the University of Toronto, was selected.

A key aspect of the survey was the desire to focus on licensing matters primarily involving corporate IP asset owners who are members of LES (USA & Canada), since participants were more readily accessible and likely to be responsive to the Licensing Foundation, and which conduct out-licensing despite being (normally) capable of directly commercializing such IP assets and in-licensing despite (normally) having its own R&D/product development capabilities. Such IP owners can be considered to be “OEMs” of licensing. Although the survey was inclusive of all members of LES (USA & Canada) with an e-mail address (5,349 e-mail addresses associated with approximately 2,669 unique organizations), and so included numerous IP service providers (1,401 of such 2,669 unique organizations were such as outside legal counsel and IP valuation organizations), the primary interest was the perspectives of such licensing OEMs (1,268, the difference between 2,669 and 1,401). Such a survey would also reach IP inventor/creator organizations such as universities and research institutes that (normally) lack the means to directly commercialize its own IP opportunities; AUTM-type respondents (universities and institutes) were included in the results reported here (albeit in small numbers). Other survey analysis which we have tested, such as royalties collected as a percentage of EBIT, used only data from commercial firms; so data from AUTM-type respondents were excluded in such calculations. Such EBIT percentage calculations are not reported here because the number and diversity of respondents does not make such analysis statistically reliable. The industry classification used by LES (USA & Canada) to group its membership was also used to classify the survey responses.

To simplify the scope of the survey we excluded licensing activities from the following areas: Right-to-Use licensing (sometimes known as “shrink wrap” licenses), cross-licensing (although we did ask some questions related to the practice), copyrighted content licensing (music, text, and the like), and trademark licensing. Further, because our database of respondents were members of LES (USA & Canada) we asked for data and perspectives for licensing activities in North America.

**Survey Format**

The survey was implemented as an online questionnaire accessible by Web browser, rather than in the traditional format of a hardcopy mail-back questionnaire. The survey was administered in January and February of 2004 by faxing a letter to the membership of the LES (USA and Canada), followed by individualized e-mails containing a link to the survey site explaining the objective of the survey. Web surveys of this type have recently been found to have comparable response rates to mail-based surveys. Web surveys also have obvious advantages over the traditional format in terms of speed, lower printing and distribution costs, and reduced data entry errors. Many individuals find that the “task burden” of responding to a Web-based survey by clicking boxes or choosing among a menu of alternatives is significantly lower than for paper questionnaires, so this format also minimizes intrusiveness and time cost. This “closed” list-based sampling frame, made up of individuals who can safely be assumed to have access to the Internet and a high level of familiarity with using Web browsers, is relatively immune to the problems with sample selection, coverage, and response biases that have been identified with some Web surveys that attempt to draw conclusions about larger and more heterogeneous populations.

Multiple iterations of the survey were tested with various volunteers who provided focus panel counsel. Such counsel resulted in significant reductions in the scope and complexity of the questions in the interest of increasing the likelihood of a larger response. Substantial dis-

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21. This section and the one following is substantially the contribution of Prof. Iain Cockburn, whose assistance is gratefully acknowledged.

Discussion took place regarding the balance between questions that asked for subjective opinion (“strongly agree,” “agree,” etc.) versus a greater (or total) focus on quantitative responses (dollars, numbers, “facts”). The resulting survey was designed to minimize any need for research numbers (to increase response rate), to be completed in not more than 20 minutes, and to be done with complete anonymity by any or multiple members of any given licensing OEM. This approach precluded the capacity to have OEM data from, say, each of the top ten pharmaceutical companies.

The Web based format also allowed us some flexibility to address the heterogeneity of the LES membership, whose involvement with various aspects of licensing varies greatly, and who belong to quite different kinds of organizations. The questionnaire was structured to serve up questions tailored to respondents answering for an entire company versus business unit, and for those engaged largely in out-licensing, largely in in-licensing, significant amounts of both activities, or indirectly involved as consultants or legal advisors. This prevented respondents from being asked redundant or irrelevant questions, speeding up the process of completing the questionnaire and further reducing the task burden.

Respondents were alerted to the general content of the questionnaire in the faxed invitation letter and follow-up e-mails, and were guaranteed anonymity. Two rounds of “reminder” e-mails were sent during the month long period that the survey was administered.

It is important to distinguish between surveys designed to elicit useful descriptive information about a phenomenon from volunteer respondents, and those designed to precisely measure population statistics. The latter requires strict “probability sampling” i.e. draw a random sample from the population of interest (e.g. dialing random digits to poll the U.S. population) and to get good results may often need “quota sampling” based on population strata and stringent controls to minimize response bias. This makes them both expensive and intrusive, and difficult to implement when key individuals with specialized information must be contacted and persuaded to willingly provide responses including confidential information. The former can usefully be done from “convenience samples” like ours, particularly when targeted at a list such as the.

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Exhibit 1. Stage 1 Dealmaking Challenges: Getting to Substantive Negotiations

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>OVERALL</th>
<th></th>
<th>LARGE ORGANIZATIONS</th>
<th></th>
<th>SMALL ORGANIZATIONS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Thinking about intellectual assets that could have been licensed in the last fiscal year but weren’t, for what percentage were potential licensees identified?</td>
<td>127</td>
<td>26%</td>
<td>54</td>
<td>21%</td>
<td>73</td>
<td>30%</td>
</tr>
<tr>
<td>Where potential licensees were identified, for what percentage were negotiations ever started?</td>
<td>121</td>
<td>27%</td>
<td>52</td>
<td>29%</td>
<td>69</td>
<td>27%</td>
</tr>
<tr>
<td>Of all the times you entered into substantive licensing negotiations in the last fiscal year, what percentage did not result in a successfully executed agreement? (Organizations engaged in significant in- and out-licensing activity only)</td>
<td>38</td>
<td>43%</td>
<td>16</td>
<td>47%</td>
<td>22</td>
<td>40%</td>
</tr>
<tr>
<td>If you had unlimited staff resources to market and negotiate additional licensing deals (above and beyond those your company has already done), what percentage more revenue do you think your company could generate?</td>
<td>143</td>
<td>45%</td>
<td>59</td>
<td>45%</td>
<td>84</td>
<td>45%</td>
</tr>
</tbody>
</table>

“LARGE” organizations defined as those with more than 1,000 employees.
LES (USA & Canada) membership made up of well-informed professionals with an interest in the outcome. But this type of information is vulnerable to response bias (those who choose to answer may not be representative of the sample) and to “frame bias” (the sample is not representative of the population it is drawn from).

A complete copy of the survey instructions and questions is available at the Licensing Foundation Website: www.licensingfoundation.org.

RESPONSE RATE

799 unique visitors to the Web site containing the questionnaire were recorded. Of these, 350 proceeded to complete at least part of the questionnaire. Of these 350 respondents, 121 were involved in licensing primarily as consultants or legal advisors, and are excluded from the following analysis. Of the remaining 229 respondents, 117 were engaged primarily in out-licensing activity, 45 primarily in in-licensing activity, and 67 were involved in significant amounts of both in- and out-licensing.

Sample selection has not yet been assessed. The “core” sample of 229 respondents is a small fraction of the total LES membership and in particular the 5,349 with e-mail addresses (as of the time period of the Survey: January 2004). However LES members are affiliated with only 2,669 distinct organizations, of which 1,401 are law firms, consulting companies, banks, or other professional service firms, and are therefore excluded from consideration here. This leaves just over 1400 “target” organizations that can be considered as the survey target OEMs of licensable IP and employ one or more LES members. Results reported here should therefore be thought of as a 15 percent sample from this reference.

It should be recognized that some of the questions posed in the survey received very low numbers of responses (50 or fewer) and the conclusions that can be drawn from these data are obviously very limited. This response rate is low, but not unusual for surveys of this nature. Studies that obtain higher response

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>OVERALL</th>
<th>LARGE ORGANIZATIONS</th>
<th>SMALL ORGANIZATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Mean</td>
<td>Number</td>
</tr>
<tr>
<td>For out-licensing, where potential licensees were identified but negotiations never started, for what percentage of these cases was it due to:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insufficient resources for the licensing function?</td>
<td>110</td>
<td>28%</td>
<td>48</td>
</tr>
<tr>
<td>Difficulty in getting internal approval to enter into negotiations?</td>
<td>106</td>
<td>14%</td>
<td>46</td>
</tr>
<tr>
<td>Valid IP but difficult for potential licensee to enforce?</td>
<td>107</td>
<td>12%</td>
<td>47</td>
</tr>
<tr>
<td>Legal/regulatory obstacles (national security, anti-trust, etc.)?</td>
<td>105</td>
<td>6%</td>
<td>45</td>
</tr>
<tr>
<td>For in-licensing, where potential licensors were identified but negotiations never started, for what percentage of these cases was it due to:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difficulty in getting internal approval to enter into negotiations?</td>
<td>26</td>
<td>27%</td>
<td>15</td>
</tr>
<tr>
<td>Insufficient resources for the licensing function?</td>
<td>26</td>
<td>14%</td>
<td>15</td>
</tr>
<tr>
<td>Valid IP but difficult for potential licensor to enforce?</td>
<td>25</td>
<td>12%</td>
<td>15</td>
</tr>
<tr>
<td>Legal/regulatory obstacles (national security, anti-trust, etc.)?</td>
<td>25</td>
<td>7%</td>
<td>15</td>
</tr>
</tbody>
</table>

“LARGE” organizations defined as those with more than 1,000 employees.
<table>
<thead>
<tr>
<th>QUESTION</th>
<th>OVERALL</th>
<th>LARGE ORGANIZATIONS</th>
<th>SMALL ORGANIZATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Mean</td>
<td>Number</td>
</tr>
<tr>
<td>Of all the times you entered into substantive <strong>out-licensing</strong> negotiations in the last year, what percentage did not result in a successful agreement due to:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inability to arrive at mutually acceptable financial terms?</td>
<td>93</td>
<td>26%</td>
<td>42</td>
</tr>
<tr>
<td>Inability to arrive at mutually acceptable non-financial terms?</td>
<td>91</td>
<td>23%</td>
<td>43</td>
</tr>
<tr>
<td>Delay in reaching agreement?</td>
<td>86</td>
<td>20%</td>
<td>41</td>
</tr>
<tr>
<td>Inconsistent positions of internal stakeholders?</td>
<td>81</td>
<td>17%</td>
<td>38</td>
</tr>
<tr>
<td>Too many parties in the negotiation (multiple licensors/licensees)?</td>
<td>79</td>
<td>5%</td>
<td>36</td>
</tr>
<tr>
<td>IP only being useful if bundled with other technology/IP that was not available?</td>
<td>80</td>
<td>4%</td>
<td>36</td>
</tr>
<tr>
<td>Licensee/licensor’s IP rights disputed by a third party?</td>
<td>80</td>
<td>7%</td>
<td>37</td>
</tr>
<tr>
<td>Of all the times you entered into substantive <strong>in-licensing</strong> negotiations in the last year, what percentage did not result in a successful agreement due to:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inability to arrive at mutually acceptable financial terms?</td>
<td>63</td>
<td>32%</td>
<td>30</td>
</tr>
<tr>
<td>Inability to arrive at mutually acceptable non-financial terms?</td>
<td>64</td>
<td>17%</td>
<td>30</td>
</tr>
<tr>
<td>Delay in reaching agreement?</td>
<td>58</td>
<td>11%</td>
<td>28</td>
</tr>
<tr>
<td>Inconsistent positions of internal stakeholders?</td>
<td>58</td>
<td>15%</td>
<td>28</td>
</tr>
<tr>
<td>Too many parties in the negotiation (multiple licensors/licensees)?</td>
<td>56</td>
<td>9%</td>
<td>27</td>
</tr>
<tr>
<td>IP only being useful if bundled with other technology/IP that was not available?</td>
<td>54</td>
<td>3%</td>
<td>25</td>
</tr>
<tr>
<td>Licensee/licensor’s IP rights disputed by a third party?</td>
<td>57</td>
<td>4%</td>
<td>26</td>
</tr>
</tbody>
</table>

“LARGE” organizations defined as those with more than 1,000 employees.
rates typically use costly (and intrusive) methods such telephone calls to non-responding members of the sample frame.

CHARACTERISTICS OF SURVEY RESPONDENTS

The respondents’ organizations varied in size from less than $1 million in annual revenues and 10 employees to more than $50 billion and 20,000 employees. On average they employed 7,863 people, had sales of $5.6 billion, and annually invested $676 million in R&D. To aid in understanding the effect of organization size, responses were analyzed separately for organizations with more than 1,000 employees (hereafter “large”) versus those with less (“small”). The average global metrics of the 96 “large” responding organizations were 18,000 employees, $13 billion in revenues, and just under $1.5 billion in R&D spending, compared to the 133 “small” organizations with 147 employees, $53 million revenues, and $41 million in R&D.

Respondents were asked whether they preferred to answer on behalf of their entire company (CO) or for a specific business unit (SBU) or division: 65 percent did respond on behalf of the CO, and 35 percent for a specific SBU.

Respondents belong to ten of the eleven LES industry categories: the largest category of respondents were in healthcare (29 percent CO respondents, 31 percent SBU), which includes biotechnology, pharmaceuticals, and biology. Approximately 22 percent of the respondents were from the combination of electronics (six percent CO respondents, zero percent SBU), energy (five percent CO & SBU), software (three percent CO, two percent SBU) transportation and mechatronics (three percent CO, two percent SBU), and “other” (seven percent CO, 12 percent SBU). The balance of respondents included university and government laboratories (14 percent CO, 21 percent SBU), and service sectors, primarily and approximately evenly divided between legal and consultants.

SURVEY DATA RELATING TO LICENSE DEALMAKING

Considering “trade” as a core element of “licensing,” one of the major areas surveyed were aspects of such dealmaking that are believed to be important or critical. Data were obtained relating to the impediments/difficulties of

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**Exhibit 4. Stage 3 Dealmaking Concerns: Look Back at Out-Licensing Deals Done**

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>OVERALL</th>
<th></th>
<th></th>
<th>LARGE ORGANIZATIONS</th>
<th></th>
<th>SMALL ORGANIZATIONS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NUMBER</td>
<td>MEAN</td>
<td></td>
<td>NUMBER</td>
<td>MEAN</td>
<td>NUMBER</td>
<td>MEAN</td>
</tr>
<tr>
<td>Thinking about your <strong>out-licensing</strong> agreements executed during the last fiscal year, with the benefit of hindsight which of the following contract characteristics would you now, on average, structure differently?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Field-of-use restrictions</td>
<td>82</td>
<td>21%</td>
<td></td>
<td>36</td>
<td>31%</td>
<td>46</td>
<td>13%</td>
</tr>
<tr>
<td>Duration of agreements</td>
<td>82</td>
<td>16%</td>
<td></td>
<td>36</td>
<td>14%</td>
<td>46</td>
<td>17%</td>
</tr>
<tr>
<td>Geographic restrictions</td>
<td>82</td>
<td>11%</td>
<td></td>
<td>36</td>
<td>17%</td>
<td>46</td>
<td>7%</td>
</tr>
<tr>
<td>Degree of exclusivity</td>
<td>82</td>
<td>27%</td>
<td></td>
<td>36</td>
<td>22%</td>
<td>46</td>
<td>30%</td>
</tr>
<tr>
<td>Most-favored-nation (MFN) provisions</td>
<td>82</td>
<td>6%</td>
<td></td>
<td>36</td>
<td>11%</td>
<td>46</td>
<td>2%</td>
</tr>
<tr>
<td>Technical milestones</td>
<td>82</td>
<td>24%</td>
<td></td>
<td>36</td>
<td>19%</td>
<td>46</td>
<td>28%</td>
</tr>
<tr>
<td>Business milestones</td>
<td>82</td>
<td>44%</td>
<td></td>
<td>36</td>
<td>44%</td>
<td>46</td>
<td>44%</td>
</tr>
<tr>
<td>Grant-back provisions</td>
<td>82</td>
<td>22%</td>
<td></td>
<td>36</td>
<td>17%</td>
<td>46</td>
<td>26%</td>
</tr>
<tr>
<td>Reach-through provisions</td>
<td>82</td>
<td>10%</td>
<td></td>
<td>36</td>
<td>8%</td>
<td>46</td>
<td>11%</td>
</tr>
<tr>
<td>Fee schedule (i.e., payment structure)</td>
<td>82</td>
<td>55%</td>
<td></td>
<td>36</td>
<td>64%</td>
<td>46</td>
<td>48%</td>
</tr>
<tr>
<td>Payment amount</td>
<td>85</td>
<td>34%</td>
<td></td>
<td>38</td>
<td>34%</td>
<td>47</td>
<td>34%</td>
</tr>
<tr>
<td>Terms of use</td>
<td>82</td>
<td>20%</td>
<td></td>
<td>36</td>
<td>25%</td>
<td>46</td>
<td>15%</td>
</tr>
</tbody>
</table>

“LARGE” organizations defined as those with more than 1,000 employees.
dealmaking at various stages: (1) getting to the point of substantive negotiations, (2) consummating such substantive negotiations, and (3) living with the deal (which may include buyer/seller remorse).

The data shown in Exhibit 1 show survey responses for both Small and Large organizations, and for both in- and out-licensing (except where noted) relating to the first two dealmaking stages. Considering Stage 1, getting to substantive negotiations, these data suggest another kind of 25 percent rule: of IP assets that (in the respondent’s opinion) could have been licensed (in the past year) only (approximately) 25 percent had been developed to the stage where potential licensees were identified, and of those assets where potential licensees were identified only ca. 25 percent reached Stage 2, initiating substantive negotiations. This result suggests that one out of eight opportunities believed to be licensable became part of serious buyer-seller discussions. In Stage 2, these data show that less than half (43 percent average of Large and Small data sets) reached consummation of a license. Coupled with the earlier stage erosion of dealmaking opportunities, this suggests that the percentage of asset opportunities that reach agreement is in the single-digits, perhaps even less than five percent. Yet, when asked what the effect would have been of unlimited staff resources, the respondents’ mean response was 45 percent more revenue than that which actually occurred. From an absolute dollars perspective, 45 percent is a significant number, but from a perspective of the large reported deal opportunity erosion, there must be other important factors than solely additional staff resources.

Considering the large disparity in size between the average Large and Small companies (the Large ones on average have nearly 250 times the annual revenue of the Small), the
### Exhibit 6. Out-Licensing Dealmaking Provisions (Tools)

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>OVERALL</th>
<th>LARGE ORGANIZATIONS</th>
<th>SMALL ORGANIZATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>What percentage of your overall number of out-licensing agreements was for a single lump sum license fee (not contingent on sales)?</td>
<td>102</td>
<td>13%</td>
<td>49</td>
</tr>
<tr>
<td>For those out-licensing deals that did include running royalty payments, what percentage used a per-unit royalty as opposed to a royalty determined as a percentage of net sales?</td>
<td>99</td>
<td>15%</td>
<td>48</td>
</tr>
<tr>
<td>What percentage of your out-licensing agreements involved milestone payments?</td>
<td>101</td>
<td>41%</td>
<td>48</td>
</tr>
<tr>
<td>For your out-licensing agreements executed during the last fiscal year, please check which of the following provisions were routinely used:</td>
<td>150</td>
<td>75%</td>
<td>63</td>
</tr>
<tr>
<td>Field-of-use Restrictions</td>
<td>150</td>
<td>51%</td>
<td>63</td>
</tr>
<tr>
<td>Geographic Restrictions</td>
<td>150</td>
<td>49%</td>
<td>63</td>
</tr>
<tr>
<td>Exclusivity</td>
<td>150</td>
<td>61%</td>
<td>63</td>
</tr>
<tr>
<td>Semi-Exclusivity (fixed number of licensors/licensees)</td>
<td>150</td>
<td>13%</td>
<td>63</td>
</tr>
<tr>
<td>Non-Exclusivity</td>
<td>150</td>
<td>51%</td>
<td>63</td>
</tr>
<tr>
<td>Non-Discriminatory (same terms for all licensees)</td>
<td>150</td>
<td>11%</td>
<td>63</td>
</tr>
<tr>
<td>“Most-favored-nation” (MFN) provisions</td>
<td>150</td>
<td>9%</td>
<td>63</td>
</tr>
<tr>
<td>Technical milestones</td>
<td>150</td>
<td>47%</td>
<td>63</td>
</tr>
<tr>
<td>Business milestones</td>
<td>150</td>
<td>57%</td>
<td>63</td>
</tr>
<tr>
<td>Onus of enforcement of IP placed on the licensee</td>
<td>150</td>
<td>33%</td>
<td>63</td>
</tr>
<tr>
<td>Grant-back provisions (rights to use improvements made by licensee)</td>
<td>150</td>
<td>41%</td>
<td>63</td>
</tr>
<tr>
<td>Reach-through provisions (royalties on sales of future products developed through use of the licensed technology)</td>
<td>150</td>
<td>31%</td>
<td>63</td>
</tr>
</tbody>
</table>

“LARGE” organizations defined as those with more than 1,000 employees.
<table>
<thead>
<tr>
<th>QUESTION</th>
<th>OVERALL</th>
<th>LARGE ORGANIZATIONS</th>
<th>SMALL ORGANIZATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>What percentage of your overall number of <em>in-licensing</em> agreements was for a single lump sum license fee (not contingent on sales)?</td>
<td>62</td>
<td>16%</td>
<td>29</td>
</tr>
<tr>
<td>For those <em>in-licensing</em> deals that did include running royalty payments, what percentage used a per-unit royalty as opposed to a royalty determined as a percentage of net sales?</td>
<td>59</td>
<td>6%</td>
<td>28</td>
</tr>
<tr>
<td>What percentage of your <em>in-licensing</em> agreements involved milestone payments?</td>
<td>61</td>
<td>44%</td>
<td>28</td>
</tr>
<tr>
<td>For your <em>in-licensing</em> agreements executed during the last fiscal year, please check which of the following provisions were routinely used.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Field-of-use Restrictions</td>
<td>42</td>
<td>79%</td>
<td>18</td>
</tr>
<tr>
<td>Limited Duration</td>
<td>42</td>
<td>48%</td>
<td>18</td>
</tr>
<tr>
<td>Geographic Restrictions</td>
<td>42</td>
<td>55%</td>
<td>18</td>
</tr>
<tr>
<td>Exclusivity</td>
<td>42</td>
<td>62%</td>
<td>18</td>
</tr>
<tr>
<td>Semi-Exclusivity (fixed number of licensors/licensees)</td>
<td>42</td>
<td>14%</td>
<td>18</td>
</tr>
<tr>
<td>Non-Exclusivity</td>
<td>42</td>
<td>38%</td>
<td>18</td>
</tr>
<tr>
<td>Non-Discriminatory (same terms for all licensees)</td>
<td>42</td>
<td>5%</td>
<td>18</td>
</tr>
<tr>
<td>“Most-favored-nation” (MFN) provisions</td>
<td>42</td>
<td>2%</td>
<td>18</td>
</tr>
<tr>
<td>Technical milestones</td>
<td>42</td>
<td>55%</td>
<td>18</td>
</tr>
<tr>
<td>Business milestones</td>
<td>42</td>
<td>60%</td>
<td>18</td>
</tr>
<tr>
<td>Onus of enforcement of IP placed on the licensee</td>
<td>42</td>
<td>33%</td>
<td>18</td>
</tr>
<tr>
<td>Grant-back provisions (rights to use improvements made by licensee)</td>
<td>42</td>
<td>45%</td>
<td>18</td>
</tr>
<tr>
<td>Reach-through provisions (royalties on sales of future products developed through use of the licensed technology)</td>
<td>42</td>
<td>36%</td>
<td>18</td>
</tr>
</tbody>
</table>

“LARGE” organizations defined as those with more than 1,000 employees.
difference in response to the questions in Exhibit 1 is small, but in some cases it may be significant. Small companies appear to have had more difficulty finding potential licensees (can’t get the attention of the right parties?), and Large ones more difficulty in consummating negotiations (because they’re more demanding?). On the question of the effect of unlimited resources, and getting from identified potential licensees to the start of negotiations, the Large and Small companies report the same percentages.

The responses of Exhibit 2 look more closely at the inability to get from the point of potential licensee identification in Stage 1 to onset of Stage 2 (negotiations). For out-licensing, the number one factor was insufficient licensing resources reported by 28 percent of the respondents, with, interestingly, no difference between Large and Small entities. For in-licensing (for which we are dealing with very small datasets), the number one impediment was internal approvals (27 percent) with again little if any difference between Large and Small companies. Getting internal approvals was the 2nd most important factor for out-licensing (14 percent), but apparently half as common a problem than finding necessary resources. Concerns about the licensee’s ability to enforce the IP was also a relatively low concern (in frequency) but occurs more often for Small companies than for Large. This result may be due to Small companies having earlier and less developed IP. Regulatory concerns were the least important of these four factors for both size categories and of lesser importance to Small companies than to Large. Concerns about IP enforceability of the IP owner/licensor in in-licensing contexts show that Large companies appear to give this far more weight than small companies. This is an approximate reversal of the reported percentages in an out-licensing context, where Small companies report a substantially higher frequency of concern regarding the licensee’s ability to enforce.

Exhibit 3 shows dealmaking break-down within Stage 2, namely the inability to consummate negotiations that have begun. For out-licensing, the top four factors, ranging in frequency of citation from 17 to 26 percent were the inability to arrive at mutually acceptable financial and non-financial terms, with financial barriers slightly more important, and the effect of delays and inconsistent positions of internal stakeholders. So the common tagline of dealmaking failure—“show me the money!”—appears to be somewhat valid (it was the highest cited factor), but there were three other factors almost as important. For Small companies, the non-financial terms and inconsistent position of internal stakeholders were more commonly cited than for Large companies. Of far lesser importance for both Small and Large companies, ranging in frequency of cause of breakdown from four to seven percent, were the effects of too many entities in the negotiation (such as a three-way, or more, deal participants), the unavailability of other useful IP, and IP rights disputed by a third party. For in-licensing contexts, the data are similar with the notable exception that nearly one third of the time the negotiation difficulties were really about the money, for both Small and Large companies. All other factors were substantially lower in importance. Also an interesting difference was a reversal of the perceptions of Large and Small companies with respect to non-financial terms in comparison to out-licensing contexts: in out-licensing, the issue of non-financial terms was cited more frequently by Small companies, but in in-licensing, it was cited more by Large companies. This is likely due to the prevalence of Small companies more engaged in out-licensing (relatively speaking) and Large in-licensing. Another factor for which such reversal is observed is the adverse effect of inconsistent positions of internal stakeholders, likely for the same reason: the buyer-seller roles are reversed.

Moving to Stage 3, living with the deal done, Exhibit 4 and 5 show the survey’s results for out-licensing and in-licensing, respectively. In both contexts the question sought to examine near term, less-than-one year post-deal, satisfaction with the deal done. This presented a kind of JD Powers “how are you liking your new car?” perspective. When considering these data we should be reminded that deals are not (normally) like victories, where there is literally a winner-take-all outcome. Deals require by their nature a mutuality of agreement, which casts a shadow, and sometimes a pall, over one’s aspirations. The parties usually recognize this situation by feeling somehow that the deal was a tie, not a victory, and yet both sides are benefited by the outcome compared to no deal. Put another way, in some ways dealmaking exhibits the famous five phases popularized by Elisabeth Kübler-Ross associated with grieving, even bereavement: denial, anger, bargaining, depression, and (finally) acceptance. If so, one would think that dealmakers looking back on less than year-old deals would exhibit a high degree of acceptance, expressed by low frequency responses as to provisions or characteristics that they would now “on average structure differently.” Yet, the data of Exhibit 4 and 5 show a relatively high frequency identification of deal characteristics that the respondent would now do differently, presumably because of both a more detached perspective away from the negotiating table and also the availability of new information from both sides of the deal.24

Looking at Exhibit 4, hindsight perspectives of out-licensing deals done, responses to 12 factors show double-digit frequencies for 11 of these factors. Only MFN provisions are in single digits, and eight of the factors are reported at percentages

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24. Another possible explanation is that these data include the perspective of deals that were done but not with the participation of the respondent. In such cases, because deals are compromises not victories, it would not be unexpected that a respondent would have a generally-critical perspective, not having been at the table and faced with the necessary horse-trading to reach an agreement.
of 20 percent or greater. Three of the factors are at percentages above 33 percent, and one was greater than 50 percent. This does not look like Kübler-Ross phase-5 “acceptance,” it is more like phase-4 “depression,” which does indeed sometimes follow “bargaining.” The top three factors reported at percentages from 34 to 55 percent all relate to “show me the money!”: fee schedule (55 percent), business milestones (44 percent), and payment amount (34 percent). It looks like the seller is most unhappy about the timing of payments, then perhaps the business events that trigger such payments, and is also quite unhappy about the magnitude of the payment, all from a less-than-one-year perspective. Given the time period of the question such disappointment is unlikely to be about royalty payments. Is it sublicensing activities and splits there from? Is it lack of licensee implementation? Next are six factors with reported frequencies ranging from 16 to 27 percent: degree of exclusivity (27 percent), technical milestones (24 percent), grant-back provisions (22 percent), field-of-use restrictions (21 percent), terms of use (20 percent), and duration of agreements (16 percent). The technical milestone concerns are likely related to the payment triggering events associated with the top three factors, but it is interesting that business milestones were a greater concern than technical milestones (44 percent vs. 24 percent) by almost a two-to-one ratio. Concerns regarding exclusivity, field-of-use, duration, terms of use, and grant-back may all relate to a form of seller remorse whereby the loss of what has been sold is more keenly felt than had been expected; perhaps this is a dealmaking version of “absence makes the heart grow fonder,” or the aphorism that the only time you’ll ever miss something is just after you tossed it out. The final three factors ranged from a low of six percent (MFN provisions) to ten percent (reach-through provisions) and 11 percent (geographic restrictions).

These data of Exhibit 4 also show a dramatic difference between Large and Small companies. For two of the factors there is a 16 and 18 point difference between the two category responses. Concerns about field-of-use restrictions and fee schedule where of greater importance to Large companies by 18 and 16 point differences, respectively. There were six additional factors where the difference in response by Large and Small companies was between eight and 10 points: three where Large companies were more concerned (geographic restrictions, MFN, and terms of use), and three that Small companies cited significantly more often (degree-of-exclusivity, technical milestones, and grant-back provisions).

Exhibit 5 provides parallel data to Exhibit 4 but for in-licensing. As with other in-licensing questions, there were substantially fewer respondents, making interpretation more problematic. In the highest frequency category were also fee schedule and payment amount, but here payment amount was the #1 factor at nearly 50 percent (49 percent), and fee schedule was close behind at 46 percent. With respect to out-licensing, the payment amount had been cited substantially less often, 34 percent, reflecting perhaps the difference in perception between paying and being paid. The next most frequent cluster ranging between 27 and 30 percent were business and technical milestones (both at 27 percent) and field-of-use restrictions (30 percent). Business milestones appear to be less of a frequent concern for in-licensing (27 percent) than out-licensing (44 percent), again perhaps reflecting on who is wearing what shoes. In the range of 12 to 18 percent were duration (12 percent), degree of exclusivity and grant-backs (15 percent), and reach-through and terms of use (18 percent). The responses concerning geographic restrictions (three percent) and MFN (nine percent) were in single digits.

Again the differences between Large and Small companies are striking with respect to certain factors. Small companies cited fee schedule concerns 67 percent of the time compared to 28 percent for Large companies, a difference of 39 points. On the other hand Large companies cited business milestone 26 points more often than Small. The only other double-digit spreads were 13 points regarding technical milestones (also more of Large company concern) and a 16 point spread for terms of use (more of a Small company concern).

DEALMAKING PROVISIONS (TOOLS)

Provisions, a common term of dealmaking art, somewhat like “provisions” as used in an expeditionary sense, are used to give the deal a designed life, anticipating the future and sometimes long-term needs and expectations of the respective parties. Switching metaphors, in pragmatic terms, provisions are really dealmaker tools. Well, what tools do our respondents use? Exhibit 6 and 7 give the frequency of use three common IP payment forms and 13 dealmaking provisions for out-licensing and in-licensing, respectively.

Perhaps most surprising from these data is the frequency of use of both grant-back and reach-through provisions, 41 percent and 31 percent, respectively, for out-licensing and even somewhat greater percentage for in-licensing (45 and 36 percent). Perhaps also a little surprising is the frequency of geographic restrictions: in this small/one-world, spaceship earth, global economy, internationalization era about half the agreements (49 percent for out-licensing and 55 percent for in-licensing) evidence geographic restrictions.

One of the interesting issues innate to dealmaking is the question of the licensee’s unbounded commercial application of the subject technology. Normally, licensee’s want the unfettered use of the licensed subject matter so that it can follow the market like a sunflower the sun, productizing and re-shaping the opportunity in whatever way the market values. The data of Exhibit 6 and 7 suggest that such unbounded freedom is granted by the seller far less often: 75 and 79 percent of the time there are field-of-use restrictions, for out-licensing and in-licensing, respectively.
Not shown in these data are some notable differences in respondents for the “healthcare” industry versus, say, electronics, with respect to the use of single lump sum license fees. As might be expected, the healthcare industry makes comparatively less use of paid up licenses, whereas paid up licenses have been commonly done in the electronics industry. In a similar fashion, the healthcare industry commonly uses royalty rates expressed as a percentage of sales whereas (for example) the electronics industry when it does make use of running royalties it more-frequently does so on some form of per-unit basis. Following this trend, the use of milestone payments is very common in healthcare, and relatively uncommon in electronics. This is believed to reflect the longer time-to-market and perhaps also the ready demarcation of various FDA stage approvals in the healthcare sector.

WHAT’S NEXT: FUTURE SURVEYS

Returning to the introductory discussion, our data for 2003 simply was not sufficiently extensive to even hint at the answer to the question of the size of the licensing industry. As stated at the outset, we surveyed only the members of LES (USA & Canada) with e-mail addresses. We made no attempt to singularize the reporting for any given company (i.e., making sure we were not double counting revenues) or assuring that every company of reasonable size reported (under confidence) their data. These tasks would be difficult to accomplish.25 Further, our sample set was useful, we believe, for the observations made here, but insufficient to make statistically reliable inferences about aggregate licensing activity.

A more expansive report of these 2004 results is expected to be published. The Foundation Web site will provide updated information on the availability of such additional information: www.licensingfoundation.org.

The original long-term objective of the Foundation’s initial attempt was to catalyze a more comprehensive understanding of this important industry, to capture not only its scale, but also its dynamism. We asked the respondents in the subject survey what questions we should have asked and did not, and we received many interesting responses, such as:

• “What percent of your IP do you present license-out? Being the licensing professional in our business I always try to maximize this while [S]BU people try to minimize it.”
• “How do you market your technology for licensing?”
• “What was the value of the deals that were done? What clinical phase were the products at the time of the license?”
• “Royalty rates paid or negotiated.”
• “How long between when the technology was licensed and when the first commercial application was released?”
• “What was the value of the competitive advantage provided by the new licensed technology?”
• “For most of these deals, the post deal management aspect is overlooked.”
• “What state of readiness for commerce when the technology that were investigated? Transacted?”
• “How often did you use reference materials on royalty rates? How often did you use [various] valuation techniques and what techniques were employed most often?”

25. Although we did not attempt to constrain reporting to one-respondent/one-company, there were in fact no detectable duplicates; however, such duplicates could have occurred because invisible SBU-parent relationships.
University Controlled Or Owned Technology: The State Of Commercialization And Recommendations

By Mark L. Gordon*

University technology transfer is the process by which a university commercializes inventions and innovations developed by university faculty and researchers. Technology transfer takes many forms, from patent licensing to forming start-up ventures on campus. University technology transfer programs are growing exponentially. Universities have long reflected upon, studied, and implemented transfer and commercialization programs. However, due to current economic and legal realities, an intense, if not completely new, era has emerged. Universities are increasing their commitment to, and support of, commercialization programs. Policies and missions have been revisited and reshaped. Campus research is exploding with applied innovation. Faculty and students are being recruited by the strength and virtue of commercialization programs. Economic pressures and competition are intense. Opportunities, as well as pitfalls, abound in this complex field. Universities that proceed with the proper balance of aggressiveness, creativity, and prudence will realize the many benefits of university technology transfer.

I. History—the Opening of the Era

University technology transfer did not gain real momentum in the United States until the early 1980s. Several forces have coalesced to raise the prominence and expansion of university technology transfer, not the least of which are the Bayh-Dole Act, the changing economy of the United States, and financial pressures on universities coupled with the potential for pay-offs from transfer programs.

The Numbers

The statistics clearly illustrate the explosive growth of university technology transfer activities over the past two decades. In 1980, universities generated about $1 million in licensing revenue. According to the most recent Association of University Technology Managers (“AUTM”) survey for the year 2001, licensing revenue for survey respondents was $1.071 billion. In 1985, 589 new patents were awarded to academia. AUTM survey respondents filed 6,812 new patent applications and were issued 3,721 new patents in 2001. During the ten-year period from 1974 through 1984, university...

1. This is not to say that university technology transfer was previously non existent. See Kenneth Sutherlin Dueker, Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies, 52 Food & Drug L.J. 453, 454-61 (1997) (briefly discussing the history of university technology transfer prior to 1980). See also, Ned T. Himmelrich and Jonathan M. Holda, Technology Transfer Agreements: Don’t Be an Amateur, 34-LEC. Md. Bar J. 30, 31 (2001).
5. Respondents to the 2001 AUTM survey included 142 U.S. universities, 28 U.S. hospitals and research institutes, 27 Canadian institutions, and one third-party patent management firm. Although the survey results did not cover all universities involved in technology transfer, nor only universities, it is nonetheless the most comprehensive study of technology transfer activities by universities available to date and clearly illustrates the increase in university technology transfer activities. The survey respondents included 92 of the top 100 universities according to amount of money spent on research activities annually. See Association of University Technology Managers, AUTM Licensing Survey: FY 2001 Survey Summary, at 5 (2003), available at http://www.autm.net/surveys/01/summarypublicversion.pdf [hereinafter 2001 AUTM Survey].
9. See id. AUTM survey respondents were issued 1,833 patents in 1995 and 2,645 in 1997.

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ties granted about 1,000 licenses total. In 2001 alone, AUTM survey respondents reported the execution of 4,058 licenses and options. From 1980 through 1993, AUTM survey respondents were involved in the formation of a total of 1,169 start-up companies. In 2001 alone, survey respondents formed 494 start-up companies.

The Bayh-Dole Act

The Bayh-Dole Act (the “Act”) governs the commercialization of inventions and innovations resulting from research funded by the federal government. It was signed into law on December 12, 1980, and became effective in July 1981. The Act was a response to an increase in global competition in technology-related fields, and was also seen as a way for taxpayers to enjoy the benefits of the investment they made in university-based research. Prior to the passage of the Act, governmental policies regarding ownership of inventions and innovations developed by entities with federal government funding lacked uniformity. Different federal agencies applied different rules. One common element of all of these government agencies’ policies was that title to the inventions and innovations funded by the government was presumed to rest with the government. This presumption proved difficult and costly to overcome, meaning that universities rarely retained ownership of inventions and innovations developed by their researchers with federal government money.

In passing the Act, Congress stated that it wanted to promote the commercialization and public availability of federally-funded inventions and innovations. In order to meet this objective, the Act, in most cases, allows recipients of federal funding to retain title to inventions developed with federal funding. Thus, universities that develop inventions and innovations with federal government funding may license them to third parties and keep the proceeds. However, the university is required to grant the government a nonexclusive, irrevocable, paid-up license to utilize the invention throughout the world. The government is also given “march-in rights” to help ensure that the public receives the benefit of the invention. This right allows the government to revoke a university’s title to any invention or innovation if it is determined by the federal agency that funded the research that the university’s commercialization efforts have been inadequate.

The Bayh-Dole Act is essential to universities’ ability to commercialize inventions and innovations developed by their researchers, because the majority of university research was, and is, funded by the federal government. AUTM survey respondents reported that 67% of their research expenditures for 2001 came from the federal government. Thus, without the Act, universities would have substantial difficulties reaping

This was in the area of federally funded research conducted by universities and small businesses. The taxpayers were getting almost no return on their investment. We came to the realization that this failure to move from abstract research into useful commercial innovation was largely a result of the government’s patent policy and we sought to draft legislation which would change this policy in a way that quickly and directly stimulate the development and commercialization of inventions.


The Act was, and is, funded by the federal government. AUTM survey respondents reported that 67% of their research expenditures for 2001 came from the federal government. Thus, without the Act, universities would have substantial difficulties reaping

21. A university must meet certain requirements in order to enjoy the benefits of the Act. For instance, the university must disclose any invention to the federal agency within a reasonable time after its development, must elect whether or not to retain title to the invention within two years of disclosure, and must file a patent for the invention within the statutory period. See 35 U.S.C. § 202(c)(1)-(3) (1994).


5. Simply put, American efforts at innovation, in which we were once the undisputed world leader, were stagnating and falling behind those of other nations. There were a number of theories on the various causes of these problems, but clearly the United States needed to develop a more effective overall technology transfer policy. Senator Dole and I agreed that there was an opportunity in one particular area where we could begin the process of providing a comprehensive technology transfer policy for the United States. This was in the area of federally funded research conducted by universities and small businesses. The taxpayers were getting almost no return on their investment. We came to the realization that this failure to move from abstract research into useful commercial innovation was largely a result of the government’s patent policy and we sought to draft legislation which would change this policy in a way that quickly and directly stimulate the development and commercialization of inventions.

the financial benefits of a great deal of their research. Likewise, the public did not receive the full benefit of this research prior to passage of the Act, because much of it was not made commercially available.\textsuperscript{25} The Bayh-Dole Act opened the door to a new era in which both universities and the general public are able to enjoy the fruits of research funded by the federal government.

The Changing U.S. Economy

For much of the 20th century, the United States had an industrial economy based on large-scale production and manufacturing, such as automobile manufacturing. In 1960, manufacturing output was 27\% of U.S. GDP and manufacturing jobs accounted for 31\% of total employment in the U.S.\textsuperscript{26} As the twentieth century came to a close, however, some manufacturing activity had moved overseas and the manufacturing firms that remain in this country have become increasingly dependent on technology to increase productivity and remain competitive. By 1997, manufacturing output was 17\% of GDP and, in 1998, manufacturing jobs accounted for 14.9\% of total employment.\textsuperscript{27} A new type of American economy has emerged. The industries that have remained in the United States are more reliant and focused on scientific and technological innovation in fields such as biomedical and computer technology.\textsuperscript{28} With this shift, the type of scientific and technology-related research conducted at universities has become more directly relevant and important to the United States’ economy. The passage of the Bayh-Dole Act represented (among other things) a recognition of this shift. Private industry also recognized this trend and has significantly increased its financial support of university research.\textsuperscript{29} Many universities have responded by embracing technology transfer and pushing for the commercialization of university-developed inventions and innovations.

Economic Payoffs/Economic Pressures

University technology transfer is “hot.” Most universities are involved, and some generate a great deal of revenue from it.\textsuperscript{30} This fact, combined with the reality of budget cuts and economic pressures faced by many universities,\textsuperscript{31} has made success in technology transfer very important to many universities.

25. While it was possible for a company to license technology from the federal government, the process to do so often proved too costly and cumbersome. “The bureaucratic red tape that accompanied any attempt at innovation was simply too great a disincentive to any company seeking to license directly from the government.” See Howard W. Bremer, \textit{Testimony on the Effectiveness of the Bayh-Dole Act}, 5 J. Ass’n U. Tech. Managers (1993), available at http://www.autm.net/pubs/journal/93/testimony93.html. Thus, a lot of important technology remained unused on the shelf, under the ownership of the federal government.


27. See id.

Clearly, the payoff for such success is potentially very significant. This potential has proven attractive to many universities.

The reasons for the growth of university technology transfer, whether it be the Bayh-Dole Act, the changing economy of the United States, economic realities at universities, or a combination of these factors, may be debatable,\textsuperscript{32} but it is hard to deny that it has grown at an amazing rate over the past two decades. A question remains debated passionately: Is this a good thing?

II. Tension of Technology Transfer with Mission

Traditionally, it has been understood that universities have a two fold mission. First, universities are charged with educating their students, and second, universities are expected to conduct research for the benefit of the public.\textsuperscript{33} Some argue that these missions can be, and in some cases are, compromised when private interests become involved in the research process and commercialization becomes the goal of research endeavors.\textsuperscript{34} Both universities and researchers stand to profit from the successful commercialization of inventions and innovations. Is the traditional mission of universities and their faculty members compromised by this fact?

Compromised Faculty?

Prior to the explosion in university technology transfer, it was generally presumed that university researchers toiled for the welfare of the general


34. See generally Shenk, supra note 29 and \textit{Press, supra note 3} (discussing many problems inherent to industry support of academic research). But see Dueker, supra note 1, 1, 470-71 (suggesting that industry does not necessarily have a corrupting influence on academics).
public, without regard to the commercial potential of their discoveries. More recently, however, it has become clear that this is not always the case. A consequence of increased university commercialization is that the professor/entrepreneur is becoming more and more common, and for good reason. Responsible faculty members now usually receive a portion of any revenue generated by their inventions or innovations.35 The Bayh-Dole Act requires that the inventor receive some share, albeit an indeterminate one, of the revenue generated from his invention or innovation developed with federal funding.36 A study from 2000 found that 28% of life sciences faculty at universities received private sponsor funding, 15% held equity in the private sponsor, 33% were engaged in paid consulting arrangements, and 32% held board positions.37 University researchers often have a direct financial stake in the outcome of their research. Some critics argue that this fact creates conflicts of interest that can compromise their research.38 Some critics even argue that university researchers sometimes choose their research topics based on the short-term commercial potential of the subject and that, because of this, important areas of research with less commercial appeal are often ignored.39 On the other hand, a study by Professor David Blumenthal suggests that, instead of having a corrupting influence on faculty members, university commercialization actually has a positive impact. The study concluded that biomedical faculty who were involved in technology commercialization taught no less, published more, produced more patented discoveries, and served in more administrative capacities than faculty not involved in technology transfer activities.40

Another matter of concern commonly raised by critics of university technology transfer is that the free flow of ideas in the academic world is stifled by the focus on commercialization of inventions and innovations. Many in the academic community insist that it is imperative that discoveries are published immediately and that information is shared openly.41 Companies that work with university researchers, on the other hand, often demand delays in the publication and sharing of discoveries and ideas.42 In order to protect the value of proprietary information, it is often necessary to avoid publication, or other forms of sharing of information and data, until proper intellectual property protection is in place. In the United States, a patent cannot be issued for an invention or innovation if it has been described in a printed publication more than one year before a patent application is filed with the Patent and Trademark Office.43 This one-year grace period is not even available in some foreign countries, meaning that any sort of publication can lead to the loss of intellectual property rights if steps are not taken to protect them.44 Likewise, any ownership or rights in trade secrets, or “know-how,” can be lost if not properly protected before the information is shared with other parties.45 The National Institutes of Health has developed guidelines suggesting that universities not allow companies to delay publication for more than two months,46 but lengthier delays are not uncommon.47 Many universities, along with their faculty members, have reacted to these concerns by adopting conflict-of-interest policies. These policies attempt to avoid conflicts of interest as much as possible, and to ensure that those conflicts that do arise do not taint research outcomes.48

Compromised Universities?

While university-industry partnerships have become quite common,49 some believe that a serious conflict in

35. See Peter D. Blumberg, From “Publish or Perish” to “Profit or Perish”: Revenues from University Technology Transfer and the S 501(C)(3) Tax Exemption, 145 U. Pa. L. Rev. 89, 101 (1996). For example, inventors at Stanford University receive 33% of the net royalties received on their licensed inventions (see Wiesendanger, supra note 33), while inventors at the University of Notre Dame receive 50% of royalty revenues after university borne expenses are covered (see University of Notre Dame Office of Research, Frequently Asked Questions in Technology Transfer, available at http://www.nd.edu/~research/techtransfer/ tfaq.html). Such arrangements, which were rare in the past, are now common at universities with technology transfer programs.


38. See Shenk, supra note 29 (discussing examples of academic research being tainted, and researchers being pressured to change research results, by companies that sponsor the research).

39. See id. (“Scientists sometimes may not pursue drugs or tests that lack obvious short-term markets”). See also Press, supra note 3, part 3. Some critics also contend that the drive toward commercialization has skewed academic research away from basic research to applied research. National Science Foundation statistics show that this argument is weak, however. The composition of academic research has remained consistent since 1980 with about 66% of research being basic science, although this is down from 77% in the early 1970s. See Richard Florida, “The Role of the University: Leveraging Talent, Not Technology,” Issues in Sci. & Tech., Summer 1999, available at http://www.nap.edu/issues/15.4/florida.htm.


41. “One of the basic tenets of science is that we share information in an open way. As biotech and pharmaceutical companies have become more involved in funding research, there’s been a shift toward confidentiality that is severely inhibiting the interchange of information.” Press, supra note 3, part 2 (quoting Steven Rosenberg, National Cancer Institute).

42. See Press, supra note 3, part 2.

43. See 35 U.S.C. § 102(b).

44. See Dueker, supra note 1, at 473.

45. See id. This type of protection, unlike patent protection, which lasts 20 years from when the patent application is filed, lasts indefinitely.

46. See Shenk, supra note 29.

47. See Press, supra note 3, part 2. See also Shenk, supra note 29.

mission arises when universities and companies partner for the purposes of research. Critics have suggested that one negative impact of this phenomenon has been a reduction in funding at some universities for departments that do not produce revenue-generating inventions and innovations, such as humanities departments. At the same time, some of these same universities have increased funding for science and technology departments. Critics suggest that this type of resource allocation, where profit is seemingly put ahead of educational opportunities and offerings, conflicts with the mission of the university to educate students and conduct research for the benefit of the public. Conversely, supporters of university technology transfer often point out the benefits of these activities, which can include upgraded facilities and increased funding for all academic departments.

Universities with exceptional technology transfer programs are also able to attract top professors and offer unique learning opportunities in technology, business, and entrepreneurship, leading to a better overall academic environment and more educational opportunities for students at those universities.

Whether one is a proponent or opponent of university technology transfer programs, it appears that such programs are here to stay. Those that continue to fight this phenomenon are likely engaged in a losing battle, although some universities have reacted to the criticism by implementing stronger conflict-of-interest policies. It should be noted, however, that these policies are not fool proof. Conflicts will exist and no policy will completely guard against them. This is a risk that universities must take or, alternatively, should avoid by not involving themselves in technology transfer. Universities that are aggressively pursuing technology transfer opportunities are fighting a battle of their own: attempting to succeed in a highly competitive environment.

III. Distinctive Technology Transfer Models

University technology transfer takes many different forms. There is no single optimal structure or mode of operation for a university technology transfer program. Universities have developed numerous models and procedures for their technology transfer programs. Some have flourished, while others have not.

University of Wisconsin-Madison

The University of Wisconsin-Madison was a pioneer in university technology transfer. The Wisconsin Alumni Research Foundation (“WARF”) was established in 1925 when nine University of Wisconsin alumni each donated $100 as capital. WARF granted its first license, for an artificial Vitamin D supplement, to the Quaker Oats Company in 1927. Currently, WARF has about 40 employees, as well as a board of 18 volunteer trustees.

In 2002, WARF claimed to have become the first university technology transfer program to open a satellite office, when it opened a branch in San Diego.

Revenue generated by WARF is distributed to the University of Wisconsin-Madison Graduate School, the inventors, and the department of the inventors. WARF contributes over $30 million each year to the University and has generated about $600 million for the University during its history. WARF received 279 invention disclosures in fiscal year 2002. The University of Wisconsin-Madison has been involved in the development of 98 technology-based companies in Wisconsin since 1995.

WARF sets up a licensing team for each invention that it accepts. The team consists of the inventor(s), an intellectual property manager, one or more licensing managers, WARF’s in-house counsel, marketing specialists, and various support staff. Outside counsel is used for patenting.

WARF uses several different methods for marketing its inventions, including the listing of available technologies on the WARF Web site, direct contact with potential licensees by WARF licensing managers, direct mailings, technical presentations made by the researchers, and participation in technology trade shows.

The Office of University-Industry Relations was established in the early 1960s. This Office works to facilitate interactions, and develop relationships, between University of

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49. See id., at 778-79 (giving examples of university-industry agreements).
50. “Universities exist to do research and research exists to benefit mankind. Companies have an additional and different agenda – making profit.” See Shenk, supra note 29 (quoting Drummond Rennie).
51. See Press, supra note 3, part 1 and 4.
52. See id., part 1.
53. See Wiesendanger, supra note 33.
55. See Duker, supra note 1, at 496.
57. See id.
58. See id.
61. See id.
62. See History of WARF, supra note 56.
66. See id.
Wisconsin research and the business/university community. The University Research Park is home to nearly 100 companies. The mission of the Research Park is to encourage partnerships between businesses and university researchers. A subsidiary of WARF, the WiCell Research Institute, was created to support research on human embryonic stem cells. A University of Wisconsin-Madison researcher, in 1998, was the first person to isolate human embryonic stem cells.

**Stanford University**

Stanford University has an established and very successful technology transfer program through its Office of Technology Licensing (the “OTL”), which was established in 1970. In fact, the program is so highly regarded that it is able to charge $1000-$2000 per hour for private tours of its technology transfer facilities. For fiscal year 2001-2002, the OTL received 315 invention disclosures, executed 112 new licenses, generated $52.7 million in total royalties, and generated over $100,000 in royalties for the year, and generated $405,000 from liquidated equity.

Some of the more prominent inventions and innovations that have come through the Stanford OTL are:
- Injectable collagen for plastic and cosmetic surgery, optimization software used in the design of yachts for the Americas Cup, the recombinant DNA “gene splicing” techniques that have given rise to the biotechnology industry, and improved FM sound systems for electronic music devices and systems.

The Stanford OTL licensing process focuses on marketing the inventions and innovations under its control. So-called “Licensing Associates,” who generally have degrees in science or engineering, experience in marketing, and prior licensing experience, staff the OTL. These associates are given complete responsibility for evaluating, marketing, licensing, protecting, and monitoring the progress of specific technologies. When intellectual property protection is necessary, the OTL seeks and selects outside counsel on a case-by-case basis based on their qualifications for the particular technology. The OTL works with Stanford’s Industrial Contracts Offices when negotiating contracts with outside parties. The Research Incentive Fund has been established by the OTL to help turn faculty discoveries into commercially viable products.

The OTL aggressively markets the services that it provides to the university community, which include intellectual property protection, marketing, licensing, and assistance with forming start-up companies. Likewise, the OTL aggressively markets the technologies under its control to potential licensees and other prospective partners. The OTL works closely with private industry in the surrounding Silicon Valley community and with companies from outside the area. It publishes a newsletter entitled *Brainstorm*, which is intended for audiences both inside and outside the Stanford community.

**University of Illinois**

The University of Illinois has a broad and assertive technology transfer program.

In fiscal year 2002, the University of Illinois had 220 invention disclosures, filed for 143 patents, was issued 42 new patents, executed 74 licenses, and generated over $9 million in licensing revenue. In addition, in the period from 2001-2002, University of Illinois faculty launched 18 start-up companies.

The University Board of Trustees created the position of Vice President for Economic Development and Corporate Relations (“VPEDCR”) to oversee and facilitate all aspects of technology commercialization for the University. Under the Vice President are two Offices of Technology Management (“OTM”) at the Urbana-Champaign and Chicago campuses. The OTMs are responsible for protecting, marketing, and licensing University-developed technology and intellectual property, and coordinate their efforts through the VPEDCR. The staff at the OTM at the Urbana-Champaign campus includes a Director, an Asst...
associate Director, several Technology Managers and attorneys, paralegals, a Patent Coordinator, and various support staff.\(^1\) Illinois VENTURES, LLC was formed under the direction of the Board of Trustees in order to facilitate the formation of start-up companies based on University technology.\(^2\) In addition, University of Illinois Research Park, LLC was formed to manage operations of research parks and business incubators run by the University.\(^3\)

In order to market its technologies, the University holds events called “i emerging” every six months. These events are showcases for its technology and start-up companies and attract venture capitalists, angel investors, researchers, and representatives from industry.\(^4\) Additionally, the OTMs sponsor technology briefings, where industry representatives are invited to hear presentations on a particular new technology.\(^5\) The Web sites for the OTMs provide a comprehensive database of University technology that is available for licensing.\(^6\) All of the above-mentioned organizations work closely together, and with private industry, in an attempt to bring University of Illinois technologies to market.\(^7\)

University of Notre Dame

The University of Notre Dame’s technology transfer program is somewhat less aggressive and structured than some of the more established programs. The Division of Technology Transfer, or ND Tech Transfer, was formed in June 1998\(^8\) and is under the University Office of Research.\(^9\) ND Tech Transfer has one full-time employee and is charged with negotiating or assisting with license agreements, new company formation, confidentiality agreements, inter-institutional agreements, collaborative research agreements, material transfer agreements, and conflict of interest matters.\(^10\) ND Tech Transfer employs outside counsel for intellectual property protection matters.\(^11\)

ND Tech Transfer is small, but growing. For fiscal year 1999, its royalty revenue was $250. This number grew to $209,000 last year and these revenue numbers have already been surpassed for the current fiscal year.\(^12\) In a typical year, ND Tech Transfer receives 30 invention disclosures, files 20 new patent applications, and executes between 10 and 20 new license agreements.\(^13\)

Notre Dame has no established formal mechanism for marketing its technologies. ND Tech Transfer gathers marketing leads from various sources, including outside companies that approach the University and the inventors themselves, which are pursued by ND Tech Transfer.\(^14\) ND Tech Transfer also works with some venture capital firms and Notre Dame’s Gigtocenter for Entrepreneurial Studies to publicize its technologies.\(^15\) In addition, the ND Tech Transfer Web site includes a list of available technologies.\(^16\)

M.I.T.

The M.I.T. Technology Licensing Office (the “TLO”) is a department of the university and reports to the Vice President of Research.\(^17\) The TLO has a staff of 31, which includes Technology Licensing Officers, Associate Technology Licensing Officers, Technology Licensing Associates, Financial Operations Staff, Information Systems Staff, Patent and Office Operations Staff, and Administrative Assistants.\(^18\) Most licensing officers have technical backgrounds and industry experience.\(^19\) Individual licensing officers manage individual technologies from beginning to end, starting with evaluation and ending with monitoring licensee performance.\(^20\) The TLO uses outside patent counsel.\(^21\)

In FY 2002, the TLO received 484 invention disclosures, filed for 245 patents, was issued 126 new patents, granted 125 licenses (including 13 trademark licenses), granted 41 software end-user licenses, started 24 new companies, and generated $33.52 million in revenue.\(^22\) After payment of any patenting costs are and deduction of a 15% administration fee for the TLO, licensing revenues are distributed evenly among the inventor, the inventor’s academic department, and the university’s general fund.\(^23\)

The TLO does not publish a list of available technologies. Instead, they use “rifle-shot” marketing, which means that they match specific technologies with the needs and interests of companies or investors.\(^24\) The TLO focuses a great deal of attention on the diligence of licensees in bringing products and services to market, generally insisting on mea-

90. See April 2002 Report, supra note 88, at 1.
93. See id.
98. Email Interview with Michael Edwards, Assistant Director for Research Development (Feb. 11, 2003) [hereinafter Edwards Interview].
99. See http://www.nd.edu/~research/.
102. Edwards Interview, supra note 98.
103. See TT FAQ, supra note 100.
104. See id.
105. Edwards Interview, supra note 98.
106. See http://www.nd.edu/~research/techtransfer/available.htm.
109. See TLO QFA, supra note 107.
110. See id.
111. See id.
113. See Pressman, supra note 54.
114. See TLO QFA, supra note 107.
The TTO has 16 employees. It receives over 100 invention disclosures and is involved in the formation of about five new companies each year. The TTO generates approximately $5.6 million yearly, which includes $2.4 million from licensing its technologies and $2.1 million from managed consulting services that it provides to academic staff members who wish to consult for external organizations. The TTO advises such staff members on issues such as costing and pricing, negotiating terms with the client company, drafting legal agreements, and invoicing. The TTO also holds equity in about 40 start-up companies based on University technology.

For marketing purposes, the TTO cultivates relationships with local, national, and international businesses and uses these relationships when appropriate in the search for licensees. Often, the researchers have relationships with potential licensees that are exploited. In addition, the TTO sometimes performs research in order to identify potential licensees and mails them a non-confidential description of the technology, which may be followed up by a phone call in order to determine interest.

IV. War Stories

Not everything has gone smoothly for all universities that have thrown their hats into the commercialization ring. Numerous cautionary tales illustrate the need for universities to proceed cautiously and prudently with regard to technology transfer activities.

The University of Florida was not prepared to take full advantage of technology transfer when a University researcher invented Gatorade in 1965. At the time, the University did not have a formal policy in place regarding the ownership of faculty inventions and, initially, had no interest in marketing the new drink. After the inventors independently reached an agreement with Stokley-Van Kamp to produce and sell Gatorade, the school decided that it did, indeed, want to be involved with Gatorade. By this time, in order to receive any of the licensing revenue from Gatorade, the University was forced to go to court and was only granted a 20% share of the profits. Although the University reportedly receives in the neighborhood of $4.5 million each year from Gatorade, it is easy to conclude that it would be receiving substantially more than that if it had formal revenue sharing agreements in place with its researchers at the time of the invention. The University’s current revenue sharing agreement with its researchers gives ownership of all inventions and innovations developed by school employees using its resources to the school and calls for the University to receive up to 70% of any licensing revenue.

The University of Arizona learned the hard way that there are risks involved in technology transfer. In 1993, a licensee of the University’s technology transfer program brought a fraud lawsuit against the University, alleging that University researchers had violated a contract in which they agreed to consult exclusively with the company, and seeking $70 million in damages. The case was settled for a reported $4.4 million, a significant sum of money especially when one considers that the University’s technology transfer program only brought in about $180,000 a year at the time.

The University of California at Berkeley was criticized for the public-relations aspect of a sponsored research and technology transfer agreement entered into with a Swiss company in 1998. The deal called for Novartis to give $25 million to Berkeley’s Department of Plant and Microbial Biology in exchange for first rights to negotiate licenses on roughly one-third of the department’s discoveries, as well as two of the five seats on the department’s research committee. This arrangement led to widespread protest and dissent within the University community by those who felt that the agreement gave Novartis too much control over University research and its results. Berkeley faced protests from both faculty and students, as well as outside groups. Petitions against the agreement were circulated, a five-part series in the student newspaper decried the deal and the growing privatization of the University in general, and a group of students protested at graduation by wearing the Novartis logo on their caps.

Boston University fell victim to too much optimism and poor investment controls when it took a large equity position in a University start-up. During the 1980s...
and early 1990s, the University invested $85 million, nearly one-fifth of its endowment, in one company, Seragen, a biotech firm founded by several Boston University professors that focused on cancer research.\textsuperscript{131} Seragen eventually failed and was sold, leaving the University with a net loss of almost $60 million.\textsuperscript{132} It was later discovered that the University’s president, as well as a number of the University’s trustees, had personally invested millions of dollars in Seragen.\textsuperscript{133}

Despite the many possible pitfalls and hurdles, most universities continue to move forward in their pursuit of technology transfer success. Some universities may proceed conservatively, but few, if any, universities have been intimidated away from technology transfer by cautionary tales such as those above—rightfully so.

\textbf{V. The Future of University Technology Transfer}

There is every reason to believe that university technology transfer will continue to grow in years to come. All of the players involved in university technology transfer in the United States, including the federal government, state and local governments, corporations, and the universities (including researchers), have many incentives to support such activities, and to continue to increase support.

The federal government will continue to support technology transfer, both through laws and with financial aid. As discussed above, university technology transfer is an important component of the United States’ fight to remain competitive in the global marketplace.\textsuperscript{134} In addition, university technology transfer adds to the bottom line of the economy. From 1980-2001, at least 3,870 new companies were formed based on university-developed technology.\textsuperscript{135}

In fiscal year 1999, university technology transfer activities contributed almost $40 billion to the economy and supported over 260,000 jobs in the United States.\textsuperscript{136} In addition, about $5 billion in federal, state, and local tax revenue was generated by technology transfer activities.\textsuperscript{137} Finally, the revenue that universities generate through their technology transfer activities supplements and invigorates government funding of university research.

For many of the same reasons, state and local governments have incentives to support university technology transfer in their areas. These governments are interested in remaining competitive on a smaller scale. They will support activities, such as university technology transfer, that lead to business and job creation, as well as tax revenue and other economic growth in their areas. In addition, state governments will support university technology transfer because it can be an additional revenue stream for cash-strapped state universities and budgets.

Corporations, obviously, will continue to increase their support of university technology transfer. By working with universities, corporations are able to gain access to advanced research facilities and talent. In addition, a lot of university research is subsidized by the government, thereby decreasing research expenses for the corporations. This is a major reason why the percentage of university research funding by corporations increased from 2.6% to 7.1% between 1970 and 1997.\textsuperscript{138} In addition, as noted, the U.S. economy has changed such that the type of research conducted at universities is more directly relevant to corporations.\textsuperscript{139}

Despite challenges, there is every reason to believe that most research universities will continue to be involved in technology transfer. Clearly, the potential to generate significant revenues via technology transfer is a strong incentive for many universities. As Pennsylvania State University economist Irwin Feller pointed out, the fastest growing source of funding for university research is the universities themselves.\textsuperscript{140} There are also more direct educational benefits from university technology transfer. Participation in such activities can be a means to lure top professors and graduate students to a university. It is also a way to teach students about entrepreneurship, and to demonstrate in a real world manner the social and commercial utility of university research.\textsuperscript{141}

Because it is seemingly inevitable that all of these forces will continue to intensely support university technology transfer, it appears that the phenomenon is here to stay and will only continue to grow. Each university will determine how it will respond to this reality.

\textbf{VI. Commercialization Guidelines}

University commercialization presents vast opportunities, but also daunting challenges. The reality is that all too many universities do not generate sufficient return from technology transfer and many others are struggling to establish effective programs. The expectations for a return are very high at the same time these institutions are budget-constrained to invest in these programs. Technology transfer is a complex landscape that requires expertise in a wide variety of disciplines. While much guidance is available, it is also undoubtedly true that given the vast environmental differences among universities, there is no one optimal structure for programs of this type. Nonetheless, each program should do no less than carefully analyze

\textsuperscript{131} See id.
\textsuperscript{133} See id.
\textsuperscript{134} See supra, Part I.
\textsuperscript{135} See 2001 AUTM Survey, supra note 5, at 14.
\textsuperscript{137} See id.
\textsuperscript{138} See Florida, supra note 39, at 365.
\textsuperscript{139} See supra, Part I.
\textsuperscript{140} See Florida, supra note 39, at 369.
\textsuperscript{141} See Pressman, supra note 54.
and focus on the following nine fundamentals.

One: Institutional Mission Alignment

A university’s technology transfer program should not, and does not have to, conflict with the mission of the university. In fact, a properly developed commercialization program will only enhance a university’s ability to achieve its mission by increasing financial resources and educational opportunities. A concerted effort should be made to ensure that a conflict with mission does not arise, both during the establishment of a technology transfer program and throughout its life. The participation of stakeholders from throughout the university community in a technology transfer program and the establishment of a conflict-of-interest policy are two important alignment considerations.

It should be kept in mind that it is likely not all members of a university community will be supportive of a university’s technology transfer program. University technology transfer has critics. Thus, in order to integrate in a healthy manner any such opposition, it is advisable to construct programs with appropriate representation from various sectors of the university community and to conduct frequent coordination and communication exercises.

Further, the development of a well-structured and comprehensive conflict-of-interest policy is a key to a successful technology transfer program. The policy should encourage commercialization of inventions and innovations, while simultaneously guarding against potential abuses or the perception of impropriety. The university’s mission statement should be kept in mind during the creation of a conflict-of-interest policy, as well as throughout the life of the program, to ensure that the operation of the technology transfer program remains consistent with the mission of the university.

Two: Program Structure and Resources

As evidenced by the case studies, a university technology transfer program can take many different forms. By way of example, if the leadership at a university is supportive of the idea of a technology transfer program, but is not enthusiastic about a large initial capital outlay to set up a program in-house, many of the necessary technology transfer functions, such as patenting, licensing, and marketing, can be outsourced to qualified third parties. On the other hand, if maintaining strict control of the program is critical and the necessary funding is available, professionals can be hired and brought into the technology transfer program full-time. Other relevant factors that may be considered when determining the structure for a university’s technology transfer program include the size of the school, the type and nature of research conducted at the university, and the number of inventions disclosed annually.

When a university technology transfer program is in its earliest stages, it may be wise to start small with many functions outsourced. As the program matures, in-house professionals and staff can be added. This strategy allows the university to avoid the large initial capital outlay required to set-up a fully functioning in-house technology transfer program. Additionally, it will allow the university to avoid mistakes in the initial structure of the program and to access the expertise of those with experience. Needs should be accurately identified and addressed slowly and methodically.

Three: Funding Sources; Projections

A university technology transfer program can be funded in many alternative manners. Usually, the university provides some level of initial funding—cash or in kind services. However, if a university cannot, or will not, budget for an adequate commitment, there are other options. For instance, individuals and private foundations sometimes fund technology transfer programs, such as in the case of the University of Wisconsin’s Alumni Research Foundation. Also, corporations may be willing to fund technology transfer operations at a university in exchange for rights or preferences in the technology that comes through the technology transfer office. Nonetheless, a long-term goal of any technology transfer program must be to become financially self-sufficient and, eventually, a source of sustained value for the university.

Financial planning for a technology transfer program is challenging. It is difficult to project a program’s income because it is impossible to predict the quantity and quality of new technologies that will be developed by university researchers. It may also take many years before a promising technology begins to generate positive cash flow, or any cash flow at all. Nonetheless, just as in any speculative venture, the process of financial planning and projecting is essential. In essence, these programs must have a business and financial plan at least as rigorous as they require for the technology that they aspire to commercialize.

Four: Identifying, Protecting, and Defending Assets

Without assets (in this case most likely intellectual property), there is no program. But the fundamentals of identifying, protecting, and defending intellectual property rights are often undernourished. A university’s property must be properly protected, even before the technology transfer program becomes involved with a particular invention or innovation. It is imperative that, at a minimum, university researchers understand the basics of intellectual property law so that the university does not unwittingly lose “control” of the
inventions or innovations by, for instance, researchers publishing the results of their research before proper intellectual property protection is obtained. It is incumbent upon the technology transfer office to ensure that researchers are supported on these matters.

Additionally, a comprehensive intellectual property policy should be developed that clearly articulates ownership and control issues, as well as obligations of both the university and the researchers. Some of the important topics that should be addressed in an intellectual property policy include, scope, ownership of inventions and innovations, income sharing formulae, disclosure mechanisms, obligations of inventors, and publication policies.

It is also important that a process through which researchers disclose inventions and innovations be developed. Generally, universities create an invention disclosure form and mandate that researchers complete such a form for every invention or innovation they develop. Some important parts of an invention disclosure form include, research funding source, detailed description of the invention or innovation, names of potential licensees in the field, disclosures of the invention or innovation made to other persons or entities, and proposed dates of publication or presentations about the invention or innovation.

Technology transfer programs will also need to take the necessary steps to secure protection of assets—by contract, securing copyright, patent, trademark, and other legal protections, and will need to consider geographic protections.146 Outside legal counsel or dedicated in-house counsel with appropriate expertise must be consulted and utilized. Moreover, no program is complete without a strategy to identify and deal with third party infringement and to enforce these hard-earned rights.

**Five: Missionary Work**

Identification and protection are essential, but marketing and distribution are synonymous with “commercialization.” University researchers need to be made aware of the existence and role of the technology “transfer” program. They need to have a sense of the value to themselves, their research, the university, and community. Thus, another essential mission of technology transfer officials must be to focus on internal marketing. This includes ensuring awareness and education for university administration, alumni, boards of trustees, and any other stakeholders whose support are needed to nurture or grow a program. Public universities should be sure to take taxpayers into account, as they are an additional group of stakeholders whose support is important. The more support the program has within the university community, and among any other stakeholders, the better. Part of the education must be that the risks of undertaking certain studies must, and will, be taken, and as with any venture, some things will go well and other things will not go so well. Methods of internal marketing and raising awareness include informational meetings, publication of inventor’s handbooks, mailings, and a technology transfer Web site. These activities should not only focus on the financial benefits of technology transfer, but also the educational benefits and the benefits to our society as a whole.

**Six: Evaluation and Valuation of Assets**

Perhaps among the more difficult aspects of university technology transfer is the evaluation, valuation, and prioritization of the inventions and innovations that are disclosed to the technology transfer office. What assets hold a reasonable chance to be marketable and under what terms? Which of the disclosures have the commercial potential such that the technology transfer program should put its precious and constrained time and resources into developing and marketing them? This process will greatly depend on the structure of the technology transfer program. Some programs are set up with this function in mind. They are staffed by licensing professionals with experience and knowledge in particular fields of technology. Other technology transfer programs have advisors that may include academics and individuals from private industry to evaluate disclosures. The use of outside consultants with expertise in the field to evaluate the commercial potential of a particular invention or innovation is also not uncommon. Once it has been determined that an invention or innovation does have commercial potential, it is sound to focus on how to derive market value—there are numerous choices.

**Seven: Marketing & Distribution Channels**

Direct licensing, ventures, alliances, start-ups, and donation are all distribution alternatives. Finding the right choice or choices (since few formats are mutually exclusive) is no small task. Researchers themselves are often good resources for information on potential partners in their particular areas of expertise. It is also important for a technology transfer office to develop a network of contacts both in private industry and in the venture capital community. AUTM is a resource for both marketing information and contacts. Some university technology transfer programs display their inventions and innovations at technology trade shows. Others, such as the University of Illinois, hold their own showcases of university technology. Most university technology transfer programs include a list of available technologies on their Web site. Whichever methods a technology transfer program chooses for marketing itself, it must be aggressive.

There are many different types of partners with whom a university technology transfer program may choose to work, including licensees, capital sources, investors, joint venture partners, consultants, and

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counsel. When choosing potential partners, it is important to carefully evaluate their skills and experience in the relevant field or discipline.147

For example, when evaluating potential licensees or joint venture partners for an invention or innovation, the goal is to find a partner that will be able to help maximize the commercial potential of the technology. An acceptable candidate should have proven skills in commercializing products or services in the relevant field, as well as a realistic plan for developing and marketing the product or service. Other important attributes to look for include contacts in the field, financial stability, and an established distribution system. It is advisable to consult with other university technology transfer programs that may have dealt with a potential partner in the past.148

Part of evaluating inventions and innovations is the determination of the optimal path to market. Often, this determination will lead to licensing the technology. However, it may sometimes be better to start a new company to develop and market an invention or innovation. Factors to be considered in determining whether a start-up is the proper path to commercialization include, whether the product or service is ready for commercialization or must be developed further, the willingness and ability of the inventor(s) to work on the marketing and development of the product or service, other available managers, and, of course, funding sources.

When looking for and evaluating capital partners and other potential investors, it is important to be both practical and prudent. It can be difficult to attract investment dollars. It is necessary, therefore, to have a realistic outlook regarding potential investors and what to expect. Nonetheless, it is important to assess carefully the skills and attributes of potential investors. Characteristics to evaluate include, the types of projects in which they have invested in the past, their experience in the relevant field, experience in the management of start-ups, contacts, reputation, and experience working with universities. Contractual terms offered by the investor must also be carefully evaluated.149 It is wise to interview multiple candidates for roles to find the professionals best suited for the desired purpose.

Eight: Documenting Transactions

No part of our commercial marketplace works without documenting understandings and expectations. Experience, knowledge, diligence, and planning are especially required at this point. Proper terms and conditions can make the difference between success and failure.

It is a good idea for a technology transfer office to develop a library of basic form contracts for different situations. This library could include exclusive and non-exclusive licensing agreements of various types (patent license, software license, etc.), sponsored research contracts, joint venture contracts, and non-disclosure agreements. These basic contracts will serve as starting points in various circumstances.

It is important to have a feel for standard terms and conditions within an industry and for the type of agreement that will be negotiated. It is also important to keep in mind that terms that may be standard in private industry may not be acceptable or standard when a university is involved. For instance, the Stanford OTL will not enter into agreements that require the university to keep all information about the license confidential, that require the university to guarantee that the invention does not infringe any patents, or that demand first rights to future inventions in the same field for a partner.150 Laws that govern public universities may preclude them from entering into contracts with terms that are deemed standard within private industry.

Nine: Consistent, Critical and Continuous Re-evaluation

University technology transfer programs are often very focused on getting inventions or innovations to market, or the “launch.” It is important to keep in mind, though, that this is not the end of the process for a technology transfer office. It is only the beginning. Continued monitoring and evaluation of both products and partners are necessary to ensure that the commercial potential of an invention or innovation is maximized and that lessons for the program can be learned and integrated. Thus, a technology transfer office should conduct regular audits of the activities of its partners. In addition, a technology transfer program should continually audit its own internal processes and make adjustments.

Conclusion

There is no conclusion. This is a very bright dawn for commercialization of university controlled and owned innovations.


148. This is true for all types of potential partners.


150. See Wiesendanger, supra note 33.
Time To Reconsider Australian And U.S. Law Regarding Exclusive Licenses Of Copyright And Patents?

BY ADAM LIBERMAN & BEN KREMER*

The Free Trade Agreement (FTA) that was recently negotiated between Australia and the United States (U.S.) has a number of far-reaching consequences for Australian and U.S. intellectual property law. One, of considerable importance to commercial practice, is the possibility that alterations will be required to the legislation of both countries regarding “exclusive licensees” of copyright and patents.

The FTA

The FTA will take effect as a treaty with the United States (U.S.), unless it is ratified by either country, and its language is still in “draft” status.1 Nevertheless, it is expected that the wording of the final treaty will not differ too greatly from the current draft.

Article 17 of the FTA sets out standards concerning intellectual property with which both Australia and the U.S. must comply. Of particular interest is the language in article 17.11.5, which requires both countries to make available to rights-holders “civil judicial procedures concerning the enforcement of any intellectual property right.” A footnote to that provision states that “the term ‘right holder’ shall include exclusive licensees,” and that “the term ‘exclusive licensee’ shall include the exclusive licensee of any one or more of the exclusive intellectual property rights encompassed in a given intellectual property.”2

At first sight, this provision seems relatively straightforward: each of the kinds of intellectual property dealt with in the FTA; i.e., copyright, trade marks, designs and patents; gives to their owner a number of exclusive rights. In general, each exclusive right deals with an act done in respect of the intellectual property (such as to reproduce a copyright work), and consists of the ability to exclude all other people from doing that act, plus the right to authorise any person or persons to do the act.

As a matter of commercial practice, those rights are often licensed exclusively by the owner of the intellectual property. Sometimes, all rights are licensed exclusively to one licensee. Other times, the rights are apportioned exclusively between more than one licensee. A matter of critical commercial importance is whether the “exclusive” licensee of a piece of intellectual property may bring proceedings against infringers of the right or rights licensed to them. Currently, the answer to this question—both in Australia and the U.S.—depends on the type of intellectual property being licensed.

However, the FTA’s definition of “exclusive licensee” expressly envisages that there may be multiple exclusive licensees of each form of intellectual property, and requires that each of them must be able to sue to enforce their exclusive rights. In essence, article 17.11.5 will require harmonisation in both Australia and the U.S. of the exclusive licensee provisions among different types of intellectual property that govern the right to bring infringement proceedings.

As a result, it is necessary to examine how well current Australian and U.S. intellectual property law fits with the approach required in article 17.11.5, as well as the practical consequences of the harmonisation that the article imposes.

Exclusive licences to copyright

Current Australian and U.S. copyright law probably conforms with the requirements of the FTA.

Australian Position

Under Australian copyright law, an “exclusive licence” is a licence from the copyright owner authorising the licensee “to the exclusion of all other persons, to do an act that, by virtue of this Act, the owner of the copyright would, but for the licence, have the exclusive right to do.”3 An “exclusive licensee” of copyright has the power to commence proceedings for infringement, subject to various conditions regarding joinder of the owner in appropriate cases.4

The concept of “exclusion” is straightforward: it requires that the act be within the monopoly granted by copyright, and that it be granted to the licensee to the exclusion of the owner.

3. Copyright Act 1968 (Cth), section 10.
4. Copyright Act 1968 (Cth), section 119.

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1. The text is “subject to legal review for accuracy, clarity and consistency.”
2. Emphasis added.
everyone else including the owner of the copyright.

The concept of “an act” is a little more difficult. It appears that the Copyright Act should be read so that the word “an act” means any activity or activities that are within the scope of the copyright owner’s exclusive rights. For example, the owner of copyright in a work has the exclusive rights to (among other things) make “reproductions” of that work (e.g., exact copies of that work), to make “adaptations” of the work (such as making translations), and also to authorise other people to do either of these acts.

Thus, a copyright owner can grant a licence to reproduce the work in printed form to one person to the exclusion of everyone else, and a licence to reproduce the work in digital form to another person, also to the exclusion of everyone else; or they may grant a licence to one person to translate the work into Russian to the exclusion of everyone else, and a licence to another person to translate the work into Spanish also to the exclusion of everyone else. Each of those licence holders would appear to come within the Act’s definition of “exclusive licensee.”

The use of the word “act” therefore appears to make it clear that the bundle of exclusive rights contained in copyright are divisible, and can be split among one or more people.

**U.S. Position**

Similarly, in the U.S., copyright consists of a number of exclusive rights, such as the right to reproduce the copyrighted work, or to prepare derivative works. Not only may each of these rights be granted to a different exclusive licensee, but it also appears that each exclusive right may be subdivided indefinitely, and each subdivision apportioned among different licensees. Provided each licensee is granted the relevant part of the exclusive right to the exclusion of all others, the licence will be an exclusive licence.

An exclusive licence to any exclusive right comprised in copyright is considered to be a “transfer of copyright ownership” in that right (whether or not it is limited in time or place of effect) and the exclusive licensee, as owner of that particular exclusive right, “is entitled, to extent of that right, to all of the protection and remedies accorded to the copyright owner.” This includes the right to bring proceedings for infringement.

**Exclusive licences to patents**

It is with respect to exclusive licences to patents that the FTA appears to require a change in the law. The FTA’s requirement that any person who holds “one or more” of the exclusive rights in a piece of intellectual property must have a right to sue to ensure that right is inconsistent with U.S., and possibly also Australian, patent law.

**Australian Position**

In Australia, the term “exclusive licensee” is defined in the Patents Act to mean “a licensee under a licence granted by the patentee and conferring on the licensee, or on the licensee and persons authorised by the licensee, the right to exploit the patented invention throughout the patent area to the exclusion of the patentee and all other persons.”

The notion of “exploiting” a patent is also defined: where the invention is a product, “exploit” includes “make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things;” and where the invention is a method or process, it includes “use the method or process,” or to do any of the above acts “in respect of a product resulting from such use.”

Slightly different language was used in the previous Australian Patents Act, and the High Court held that under that Act there could only be one exclusive licensee of a patent, and that to be an exclusive licensee, the licensee had to be granted all of the relevant rights under the patent. So, a licensee who only had the exclusive right to make a patented product, or to import a product made by a patented process, was not an “exclusive licensee” for the purposes of the previous Act. In such a case, despite the intention of the parties, only the patent owner could commence proceedings for infringement of the patent.

It is unclear whether this approach will be adopted for the current Patents Act, which is worded slightly differently. So far, the proposition has been examined in only one case, which suggests that under the new Act a licence of only some of the patent rights may be an exclusive licence under the Act. The decision is of a single judge, sitting at first instance, and it is unclear whether the basis of the decision will ultimately be accepted by higher courts. If it is, then Australian patent law will be consistent with article 17.11.5 of the FTA. If not, then legislative change will be required.

**U.S. Position**

It seems clear that the position in the U.S. is virtually identical to the position under the previous Australian Patents Act. The U.S. Patent Act grants a “remedy by civil action for infringement of [a] patent” only to

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6. Silver v. Sony Pictures Entertainment, Inc., 330 F.3d 1204 (9th Cir. 2003). See 17 U.S.C. § 201(d)(2): “[a]ny of the exclusive rights comprised in a copyright, including any subdivision of any of the rights specified by section 106, may be transferred as provided by clause (1) and owned separately.”


11. Although the list of actions constituting “exploiting” an invention now reads disjunctively, in contrast to the previous Act, the current Act still refers to “the right” to exploit the patented invention. Such a reference in the previous Act was one of the factors that led the High Court to insist that there could be only one exclusive licensee of a patent. Arguably, unless the licence contains all the rights listed in the definition of “exploit,” it might not be a “licence to exploit” the patent at all, and hence cannot be an “exclusive licence.”

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the “patentee,”12 and to “successors in title to the patentee.”13 Subsequent case law has confirmed that an exclusive licensee of a patent can also sue for infringement (provided additionally that they join the patentee), because such a licensee has “all substantial rights” to the patent, and so is effectively an assignee of the patent (i.e., a successor in title to the patentee).14

However, such a licensee must actually have all substantial rights; a licensee of a patent who does not have “all substantial rights” under the patent is not an exclusive licensee (but a mere licensee), and does not have standing to sue in the U.S. for infringement of the patent.

Contrast: United Kingdom Copyright and Patent Law

The above should be contrasted with the position in, for example, the United Kingdom, where multiple exclusive licences can be granted to both copyright and patent. An exclusive licence to copyright consists of an exclusive grant by the copyright owner to another “to exercise a right which would otherwise be exercisable exclusively by the copyright owner;”15 while an exclusive licence to a patent involves the exclusive grant (i.e., to the exclusion of all other persons, including the proprietor or applicant) of “any right in respect of the invention to which the patent or application relates.”16

A licensor’s ability to control its exclusive licensees’ lawsuits

If Australian and/or U.S. patent law is changed to allow there to be multiple exclusive licensees of a patent, an important commercial issue arises: can a licensor remove the ability of an exclusive licensee to bring infringement proceedings, and if so, how? The identical issue arises in the copyright context, even though no change in the law is required.

In a commercial context, a licensor may wish to prevent the possibility that one exclusive licensee can take action against another exclusive licensee, or against a third party. This might be the case, for example, where the licensor has commercial relationships with a potential defendant that it wishes to protect. Alternatively it might wish to reduce the chance that the validity of the patent will be challenged by a defendant to a patent infringement suit, which is a common defence tactic in such suits.

At least two issues arise. One involves the ability of private parties to contract out of rights granted in public statutes. The issue is illustrated in its diametrically opposed forms in the Australian Trade Marks Act, which specifically provides that the rights of an authorised user—whether exclusive or not—are subject to contract between the licensor and authorised user, and the Trade Practices Act, which specifically provides that certain rights granted by that Act cannot be contracted out of.17

Current Australian copyright and patent law, however, are silent as to whether the rights of an exclusive licensee to bring infringement proceedings can be contracted out of. Given the review process brought about by the FTA, it would seem an opportune time for this issue to be resolved.

A second issue is whether any limitation on the exclusive licensee’s right to sue might in fact make the licence non-exclusive. Currently, given the definition in U.S. patent law, there is a good argument that any licence granted to a licensee that does not give the licensee unfettered power to sue for infringement is not a grant of “all substantial rights” under the patent, and hence not an “exclusive licence.”18 The preferable course here would seem to be to adopt language similar to the Australian Trade Marks Act, in which a person may be an authorised user—whether exclusive or otherwise—notwithstanding that their rights under the Act are subject to modification by the parties. Therefore, absent any cogent policy reason, the principle of freedom of contract should prevail.

Conclusion

It appears that neither Australian nor U.S. copyright law regarding exclusive licensees will require amendment as a consequence of article 17.11.5 of the FTA. It is doubtful, however, that the same can be said of Australian and U.S. patent law in that area. In both cases, however, there would be merit in amending the copyright and patent legislation of both countries to expressly deal with whether exclusive licensees’ rights to bring infringement proceedings may be modified by contract.

17. Trade Marks Act 1995 (Cth), section 26; Trade Practices Act 1974 (Cth), section 68.
What is Biotechnology?

Biotechnology is the “use of cellular and molecular processes to solve problems or make useful products.”

Biotechnology can be applied to basic scientific research, development of healthcare products (therapeutics, devices, and diagnostics) and services, agriculture, and nutraceuticals.

The Clinical Development Process

It is important to have an understanding of the clinical development process for human therapeutics. It is through this process that compounds identified by scientists are approved for human use (for specific purposes) by regulatory authorities. Each country has a regulatory authority such as the Food and Drug Administration (FDA) in the U.S. and the Health Protection Branch (HPB) in Canada. Clinical development risk is the largest business risk facing biotechnology companies.

We have provided an overview of the clinical development process in the Appendix.

Companies are Made up of a Group of Products

Generally a biotechnology company is a collection of one or more market opportunities or products. Therefore to value a company, each one of the products must be valued. The value of the company is then determined by adding up the value of all the products and the company’s other assets and liabilities. Sometimes companies indicate that they have a “platform” technology with a large number of possible products or services. Management must decide where to allocate their resources and therefore which opportunities to pursue.

Two Major Stages of Product Life:

There are two major stages of a product’s life:

1. Research & Development Stage, and
2. Commercialization Stage.

The cash flow for each of these two periods can be estimated separately. It is quite usual for a valuation analysis to start with the second major time period component. By starting with the second component, the analyst can quantify the eventual market opportunity. This is how many companies begin their analysis when determining whether it makes economic sense to even contemplate starting the clinical trial process. This is the payoff! This is the opportunity sought. This is the reason to invest. The opportunity needs to be there to justify the investment to be made in clinical trials. Certain companies have minimum market opportunity sizes before they will even begin to consider whether to pursue an opportunity.

Therefore, this is how we begin our analysis.

Step One: Start with Commercialization Stage

To determine the value from market launch to the end of the product life, estimates of the following are made:

1. The forecast cash flow from market launch until the end of the product life.
2. The discount rate to apply the cash flows.
3. The net present value at the market launch date is then determined by applying the discount rate to the forecasted cash flows.

The forecasted cash flow from market launch to product expiry (product life) requires a quantification of:

1. Expected revenue;
2. Cost of sales;
3. Operating costs; and
4. Income taxes.

For the purposes of this summary article we have made a simplifying assumption that the value of the opportunity at market launch is $1 Billion.

Step Two: Value back through R&D Stage

The expected future cash flow during the development stages until market launch is made up substantially of the costs of pre-clinical trial research & development and conducting the clinical trials related to the specific indication. Therefore, the valuator must make an estimate of the:

1. Cost,
2. Timing, and
3. Risks;
of each of the stages of the pre-clinical and clinical trials.

A detailed understanding of the clinical trial process is critical. See the Appendix to this article for an outline of the clinical trial process. Understanding all the parameters and risks associated with the clinical trial process is a major task of the valuator.

Key documents that articulate a clinical trial plan include the “Investigator’s Brochure” including the “Protocol.”

**Cost**

Detailed build-up of the budgeted trial costs

A bottom-up estimate of the cost of clinical trial is used to determine how much cash is needed. A complete detailed budget should be prepared by management and should be reviewed by the valuator for reasonableness, as part of the assessment of the forecast.

The costs of a clinical trial include:

1. Trial design;
2. Patient recruitment;
3. Investigator and clinician costs;
4. Pharmaceutical product;
5. Monitoring costs;
6. Data analysis;
7. Close out & reporting results;
8. Coordination with regulatory authorities; and
9. Administrative costs.

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3. If no forecast is available, one will have to be prepared using the structure outlined in this article.

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Table 1. Historical Rates of Success of Clinical Trials

<table>
<thead>
<tr>
<th></th>
<th>Small Molecule&lt;sup&gt;4&lt;/sup&gt;</th>
<th>Protein Therapeutic&lt;sup&gt;5&lt;/sup&gt;</th>
<th>Monoclonal Antibody&lt;sup&gt;*&lt;/sup&gt;</th>
<th>Mark Struck&lt;sup&gt;7&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>73%</td>
<td>75%</td>
<td>84%</td>
<td>88%</td>
</tr>
<tr>
<td>Phase II</td>
<td>45%</td>
<td>50%</td>
<td>72%</td>
<td>86%</td>
</tr>
<tr>
<td>Phase III</td>
<td>Not separately quantified</td>
<td>73%</td>
<td>Not separately quantified</td>
<td>93%</td>
</tr>
<tr>
<td>Regulatory Approval</td>
<td>Not separately quantified</td>
<td>81%</td>
<td>Not separately quantified</td>
<td>Not separately quantified</td>
</tr>
</tbody>
</table>

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Other Costs

Other administrative costs must also be included in the budget such as the premises, equipment, management salaries, intellectual property and legal fees. These are some of the more typical other costs incurred during the development process.

Overall it is helpful to consult a number of different members of the management team in reviewing management’s forecast. Key personnel include the director of clinical trials, the chief scientific officer, the chief financial officer and the president.

Timing

Timing of the clinical trials is a function of the length of time required to conduct the trials and the amount of time it takes to get the relevant publications and necessary regulatory approvals. The length of time that a trial takes is a function of: number of patients, speed of recruitment, natural disease progression and amount of time it takes for the therapeutic to show efficacy versus natural disease progression.

Estimates of trial timing can be determined through a review of the clinical trial protocol and discussions with participating clinicians. Estimates provided can be compared to trials of similar indications at similar stages of development. The Appendix to this article provides some general guidance.

Risks

Applying A Decision Tree to the Clinical Development Process

One of the major risks in the development of biotechnology is the clinical development process. Each stage of a clinical trial is a step along the journey to obtaining market approval from the regulatory authorities. By assessing the probabilities of achieving success at each stage of the clinical development of a therapeutic, the specific risk can be quantified directly in the valuation model.

A basic decision tree with the probabilities of making it through each of the clinical trials is shown in Chart 1.

For each of the stages of development there is a probability of that stage being successful and unsuccessful. For example in the above tree, we have assessed the probability of success for phase I at 75%.

Sources for Determining Probabilities of Success for Each Stage of the Clinical Trial

The primary source for analyzing

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the probability of successfully moving through each of the stages of the clinical trials is discussions with the management of the company and designers of the trial.

In addition, to help put this analysis in a context, there are a number of publications that show analyses of probabilities of achieving success through each of the clinical trial stages, as shown in Table 1.

**Determining Net Present Value**

Once all of the above analysis is complete, the valuation is a simple matter of taking the NPV at market launch and then discounting it back through the decision tree and deducting the present value of the clinical trial costs as you go. Because the biggest risk has been directly quantified using the clinical trial probability of success, we use a more typical discount rate. In this case, we have selected 12%.

Continuing on with the example developed, the values at the beginning of each of the phases of clinical development, as shown in Chart 2.

### Value of a biotechnology company through its life-cycle

Using the above data, the following chart shows the effect of the successful outcome of clinical trials on the value of a biotechnology company. These significant jumps in valuation are reflected in the stock prices of publicly traded biotechnology companies that achieve clinical milestones.

### Reasonableness Check on Conclusions—Other Methodologies

As a reasonableness check on the value conclusion, it is helpful to apply one or more market approaches to value. In order for the market approach to be useful the comparable deals should be as similar as possible to the subject of the valuation. Factors to consider in determining similarity include:

1. Stage of clinical development, disease target,
2. Status of intellectual property, and
3. Other products in development.

The following is a very brief summary of four market approaches that are used by biotechnology analysts:

1. **Comparable Licensing Transactions**: the present value of the upfront payments, milestone payments and expected royalties is calculated as an estimate of value.
2. **Comparable Venture Capital Transactions**: implied pre-money valuations are calculated based on dollars invested and percentage of company received by VC Fund.
3. **Mergers & Acquisitions**: implied valuations of acquired companies.
4. **Stock Market**: implied technology values, (market cap less net assets).

### Conclusion

The major risk to be quantified in the valuation of biotechnology is the risk of successfully completing clinical trials. Therefore we have found that the decision tree discounted cash flow method is often used, as it reflects how the managers and investors in biotechnology companies assess their investments and manage their business.

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**Appendix. Understanding the Drug Development and Clinical Trial Process**

<table>
<thead>
<tr>
<th>2-3 Years</th>
<th>1 Year</th>
<th>6 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>An Average of 10 Years</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Research</strong></td>
<td><strong>Preclinical Development</strong></td>
<td><strong>Clinical Development</strong></td>
</tr>
<tr>
<td>Idea ▼</td>
<td>To assess:</td>
<td>Phase I</td>
</tr>
<tr>
<td>Target ▼</td>
<td>- Safety</td>
<td>To evaluate:</td>
</tr>
<tr>
<td>Hit ▼</td>
<td>- Biological activity</td>
<td>- Pharmacokinetics</td>
</tr>
<tr>
<td>Lead ▼</td>
<td></td>
<td>&amp; pharmacodynamics</td>
</tr>
<tr>
<td>Candidate Drug</td>
<td></td>
<td>(absorption, distribution, metabolism &amp; excretion)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Safety</td>
</tr>
<tr>
<td>Laboratory</td>
<td>Laboratory &amp; animal studies</td>
<td>Phase II</td>
</tr>
<tr>
<td>20-50 healthy subjects (patients in specific cases)</td>
<td></td>
<td>To evaluate:</td>
</tr>
<tr>
<td>100-300 patients suffering from the disease the drug is intended to treat</td>
<td></td>
<td>- Efficacy</td>
</tr>
<tr>
<td>500-5,000 patients suffering from the disease the drug is intended to treat</td>
<td></td>
<td>- Safety</td>
</tr>
<tr>
<td>&amp;</td>
<td></td>
<td>- Optimal dosage &amp; regimen</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Safety of long term use</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Review &amp; approval by regulatory authorities</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- The drug is made available to the public</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Post marketing studies pharmaco-vigilance on a long term basis</td>
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Source: Biochem Pharma, 1998 Annual Report
The Management Of Intellectual Property In Australia

BY ADAM LIBERMAN*


INTRODUCTION

IP management can be viewed along a spectrum. One end of the spectrum reflects the position that IP management is simply ceasing to deal with intellectual property on an ad hoc basis; the other end views IP management as a vital and essential strategic tool. IP management can therefore mean different things to different organisations.

I am going to provide an overview of IP management both in an Australian and a U.S. context in order that you can consider where along that spectrum your organisation does, or should sit, if it wants to sit anywhere at all.

I am also going to argue strongly for the proposition that proper IP management is an important and undervalued component in Australia’s aspiration to successfully commercialise its “inventiveness.” It is the missing infrastructure between “research and development” and “commercialisation.” Australia’s deficiencies in commercialisation have, however, long been recognised. The IP management gap however, has not, and this needs to be clearly addressed.

I will consider the rationale, purposes, elements and variables relating to IP management. I will also make some observations about IP management in the Australian context, as well as identify what action is required at a policy level in order to bring IP management into greater focus.

RATIONALE

There is a value based rationale for IP management which is reflected in Chart 1, sourced from the Brookings Institute, and from some figures referred to below:

Specifically, we are talking about the use and ownership of subject matter which does and can give rise to significant value. That value is reflected in the U.S. corporate context as part of the growing portion that intangible assets make up of the S&P 500. No study that I am aware of has undertaken the further step of identifying what portion of those intangible assets comprise intellectual property, but I would be surprised if that portion did not amount to a significant value.

I am also not aware of any similar study being done in Australia, but again I would think there would be a certain comparability with the U.S., in that intangible assets as the first layer and intellectual property as a subset of that layer, are likely to form a significant portion of our Australian Stock Exchange companies. Therefore, just like any other type of asset, intellectual property needs to be properly managed in order to maximise its value.

Another example of that value based rationale is, the very size of the value of output created using intellectual property rights—such as licensing income—and the very size of factors adversely impacting on the value of that output, such as impairment and infringement. This again means that intellectual property is an appropriate subject for proper management, and not just another legal right to be dealt with on an ad hoc basis.

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The figures set out below are estimates from the U.S. intellectual property merchant bank, ICMB Ocean Tomo:

**U.S. Estimates**

- Over US$100 billion annually collected in Intellectual Property licensing income.
- Over US$200 billion annually written off from Intellectual Property impairments.
- Over US$300 billion annually in unpaid infringements.

Whilst these figures are large, they clearly do not take into account a whole range of other value creating activities involving the use of intellectual property, e.g. securitisation based on intellectual property rights, sale and purchases of intellectual property rights, use of intellectual property in corporate structuring, etc.

Increasingly also organisations are thinking about intellectual property in the context of risk management. Amongst the risk areas, particularly in the United States (a market that most Australian businesses aspire to enter), licensors have been held to be liable for the activities of their licensees. Additionally, in the United States, I understand that the existence of overseas registrations can significantly add to the value of the licence.

**Purpose**

The nature of IP management can vary significantly, depending upon its purpose or purposes. The three purposes that I usually encounter are the following:

**Extraction of maximum value for benefit of relevant stakeholders**

The nature of the value to be extracted differs depending upon the nature of the organisation being considered. Thus, at the extremes, a purely profit motivated organisation will have a different concept of value to a purely “public good” motivated organisation and as such a different concept of the value that each would seek to extract for their relevant stakeholders.

**Risk management**

Increasingly also organisations are thinking about intellectual property in the context of risk management. Amongst the risk areas, particularly in the United States (a market that most Australian businesses aspire to enter), licensors have been held to be liable for the activities of their licensees. Additionally, in the United States, I understand that there is a growing trend to intellectual property based class actions by shareholders. Those actions include allegations about misleading statements and prospectuses concerning patents and false claims about the exclusivity of licences.

In Australia, there is no reason why the provisions of section 180 of the Corporations Act, relating to the duties of directors, could not apply to directors of a company if those directors do not fulfill their duty concerning the management of a company’s intellectual property and that company thereby sustains a loss.

There is also a growing friction between employer and employee rights in intellectual property which is illustrated by the recent Federal Court case of *Victoria University of Technology v. Wilson*. That friction could be minimised by better intellectual property management practices.

These are obviously not the only risks that need to be considered. A hierarchy of the principal risk areas likely to affect an organisation need to be properly identified in order to deal with this purpose.

**Record keeping**

Finally, whilst record keeping may seem to be the simplest purpose to implement, you may be surprised to know the number of transactions that I am aware of where delay and significant additional costs were incurred because details of an organisation’s intellectual property were not in order—simple things like not recording an assignment or forgetting the existence of overseas registrations can cause unnecessary problems.

Importantly, the above purposes should not be considered to be either mutually exclusive or exhaustive. Additionally, whatever purposes are identified as relevant to a particular organisation’s IP management, the success or otherwise of that management should be judged against those purposes and not others.

**Elements**

**Legal rights**

A crucial component of a successful IP management strategy is the recognition that intellectual property is a bundle of legal rights and that those rights can be complex and differ from country to country. Thus, whilst an organisation may well have excellent systems in place to deal with whatever issues they are intended to deal with, if the appropriate legal input is not built into those systems, they will be of lesser or nil value depending upon the circumstances.

For example, it may be important to know and deal with the fact that co-ownership of patents is dealt with differently under the Australian law, than it is under U.S. law. It may also be important to know things such as:

- (a) just because your organisation is referred to as an “exclusive licensee” under a patent licence, that will not necessarily mean that it will have the rights of an “exclusive licensee” under relevant patent legislation;
- (b) an obligation to pay patent royalties which extends beyond the term of a relevant patent, will not be
enforceable in the U.S.;

(c) in Australia, the entirety of an agreement may be brought to an end if one of the patents that is licensed under it is no longer in force – and this, even though the agreement may deal with a much wider range of subject matter than just patents;

(d) in Australia, that registered trade marks cannot be assigned for a part of Australia, but patents and copyrights can be; and

(e) registered trade marks are the only form of registered intellectual property right that can have an unlimited term.

The list of these sorts of examples can literally go on forever and that is why having appropriate legal input at the appropriate time is particularly important.

Leadership

Another crucial element of a successful IP management program is that leadership of the relevant organisation participates in, endorses and champions the program, e.g. if education sessions are conducted, the relevant leaders of the organisation should be seen as active participants in those sessions.

Education

Education sessions cannot be one off, must be part of the induction program of an organisation, must be given at least equal priority to any other education programs conducted for staff in an organisation and cannot rely solely on on-line learning as its basis. The education sessions should be conducted by both internal and external personnel; the external personnel being particularly important to provide both fresh ideas and reinforce existing good practices that derive from experiences outside your organisation.

Resources

In an extensive study of U.S. industry by Petrash Williamson entitled “Strategic and Operational Management of Intellectual Property Benchmark Report,” in keeping with the value proposition mentioned at the outset of this talk, it was found that:

“Generally intellectual property is recognised as an important component of [a] company’s value. There is [however] a gap between this recognition and providing the resources needed to effectively manage...IP portfolios.”

Anecdotally, in Australia that recognition of value varies from organisation to organisation. Proper resourcing will be dependent upon the extent to which the following propositions prevail:

- That measurable returns are required from an investment in IP management.
- That there is inherent merit in properly managing IP without necessarily having all the metrics to prove it.

I discuss the important issue of metrics below, but in the meantime, highlight another key point in the resources debate. The key point is that the “resources debate” appears to be based on the incorrect premise that all the relevant resources have to be made available at the one time. When viewed in that light the cost of implementation can be viewed as prohibitive. If, however, the establishment and maintenance of a proper IP management regime was viewed as an incremental exercise, the cost of resourcing it is less likely to be viewed in such extreme terms.

Alignment with organisation’s strategy/business plan

Just as all other aspects of the management of an organisation need to be aligned to that organisation’s strategy and business plan, so the management of an organisation’s intellectual property needs to be so aligned. The issue is not whether this is a correct approach to adopt, rather the issue is how best to implement that approach. The principal difficulty in such implementation, in my experience, derives from two sources. Firstly, that intellectual property has traditionally been viewed principally as a legal function; this in turn means that it has been viewed as a place where costs are incurred rather than revenue earned. Secondly, there is little in the way of management tradition and skills for dealing with it.

Before I suggest some methods for creating the alignment sought, I give an example of the potential benefits of such alignment.

Company A identifies a market need that if met would bring about anticipated revenue on a worldwide basis of $1 billion per annum. Patent and design searches are undertaken to determine the extent to which such a product is already covered by published patent applications, granted patents or designs.

Company B is identified as having significant coverage in this area. Investigations into Company B’s actual market activities in this area reveal that none of the relevant products are yet available on the market and further that Company B’s financial position means that it is unlikely that it would have the resources on its own to bring such products to market in the near future.

Company A considers the following options:

- Acquiring Company B;
- Acquiring the patent/design portfolio;
- Licensing the patent/design portfolio;
- Approaching Company B to form a joint venture;
- Employing the principal inventors/designer of Company B disclosed in the patents, etc.

From this example, one can see that there is an interaction between the creators of the relevant strategy/business plan and those who deal with IP management for Company A. It is that interaction between those who face the market or are responsible for an organisation’s activities in the market, and those involved in or responsible for IP management that is crucial to bringing about that alignment. How this interaction best occurs will differ from organisation to organisation. In the Australian Nuclear Science and Technology Organisation (ANSTO), a research based organisation, there is a Patent Management Committee that comprises ANSTO business development people, ANSTO intellectual property management people, ANSTO scientists, as well as qualified...
persons external to ANSTO who are bound by confidentiality undertakings. ANSTO Business Development supports the patent protection costs for inventions recommended by the Patent Management Committee for up to 18 months after filing the initial patent application. During the 18 month period inventions with recognised commercial potential identified by the Patent Management Committee will progress further through the ANSTO business development process.

In other organisations, IP management reports to relevant business units; in others, there is a regular interaction with marketing departments; in others, the head of IP management sits on the body within the organisation responsible for developing strategy and business planning.

Having made it sound relatively easy to achieve this alignment, it is heartening to a certain extent to find that in the U.S. context, that alignment is also not being easily achieved. Thus, amongst the conclusions of the above mentioned Pettrash Williamson study, are the following:

“Intellectual property is not very well aligned with the business strategies of the survey companies...”

“Not a lot of management processes are in place to assure alignment of intellectual property tactics and that actions are aligned with the business strategy.”

Heartening as those conclusions may be, in that they perhaps indicate we in Australia may not be that far off the pace, this is where the greatest return from IP management can be achieved, i.e. aligning the tools that can provide exclusivity and protection with where the greatest market return and market need lies, and therefore providing the necessary infrastructure between creativity and commercial success.

Inventory, valuation and audit

There are a few simple points that I would like to make in relation to the elements of inventory, valuation and audit. Firstly, you need to know what you have before you can manage it, and as such, the need for an inventory. Secondly, you need to keep that inventory up to date otherwise it will lose its relevance. Thirdly, separately from any accounting requirements, attribution of value is a proxy for determining priorities in management, and is therefore a useful tool to have. Fourthly, by audit I mean a regular review of the inventory to determine its relevance to the organisation’s strategy. Fifthly, using the opportunity presented by the introduction of the new accounting standards for intangible assets, commencing 1 January 2005, as a springboard to create an intellectual property inventory and therefore as a cost effective incremental step in developing an IP management program.

Monitoring competitors’ activities

There are a number of reasons for monitoring competitors’ activities in relation to intellectual property. The first is that for registrable rights such as designs, patents and trade marks, filings may be a useful pointer to the direction that competitors may be heading. The second is to prevent your competitors from obtaining certain rights, e.g. through an opposition process. The third is to determine the extent to which your competitors may be infringing your rights.

All of these are legitimate reasons and all of them should be considered in any monitoring program.

The Pettrash Williamson study found that:

“Most companies routinely monitor their competitors’ patent activities.”

Without in any way being exhaustive, in my experience, trade mark monitoring has been used as an early warning device by pharmaceutical companies concerned about the activities of their generic competitors and by consumer companies to determine the next line of snack food that their competitors are likely to introduce. Design registration filings have been used by shoe companies in the youth market to determine where the market leader is heading.

Separately from monitoring the filing activities of your competitors in the actual geographic market that you compete in, monitoring the activities of market leaders in other markets can also be advantageous, particularly if you know or it is likely that those market leaders will take little interest in the Australian market or other geographic markets relevant to your interest.

Enforcement

An organisation will need to develop a mindset about enforcement that there is no such thing as the “self-enforcement of rights,” i.e. that obtaining the relevant rights is only part getting the benefit of those rights. An important part of creating that mindset within an organisation is the allocation of a budget for dealing with such contingencies. This provides a clear signpost for the organisation that some money may need to be spent and therefore some action may be required. Budgeting for such a contingency should not be viewed as other than a normal feature of an organisation’s budgeting process.

The development of a policy for dealing with enforcement should preferably be characterised in terms of “protecting an organisation’s assets” rather than “dealing with infringements.” The former is a characterisation which makes it an issue for the organisation as a whole, rather than an issue just for the organisation’s lawyers, and as such, something removed from the organisation itself.

Whilst the policy should be uncompromising in terms of protecting an organisation’s intellectual property, it should also recognise that in many instances infringements are inadvertent and that therefore they can usually be dealt with by well drafted letter from the organisation itself. If such a letter and follow up steps do not achieve the desired result, then the policy should clearly identify a process for the matter to be escalated. The policy should be appropriately disseminated within the organisation.

Three particular features of enforcement are worth commenting on. Firstly, any letter of demand that
is written should not arm the recipient with a means of attacking your organisation on the basis the letter contains what are known as “unjustified threats.” Unjustified threats are actionable in their own right in many jurisdictions, including Australia. Secondly, all your communications with your professional advisers should ideally be protected by legal professional privilege, i.e. it is preferable for advice to be obtained through your lawyers and not through other professionals such as accountants. Finally you should be prepared and factor into your attack on any alleged infringer that they may seek to counter by attacking your intellectual property rights.

In simple terms, all of the preceding means that enforcement should be thought of in proactive terms rather than reactive terms, i.e. something you control, rather than something that controls you.

**Incentives**

There is no IP management program that I have encountered which has not had an incentive component of some sort built into it. Incentives range from financial to non-financial and can focus anywhere along the spectrum from creation of relevant subject matter, to that subject matter encountering the market place. None of the incentive components that I have seen, however, relate to adherence to or developing improvements to the IP management process itself. I think that these latter activities are just as worthy of consideration, to the extent that they can have a positive impact on the principal focus of the incentives.

As to what the incentives should target, there are three principal areas which require consideration:

(a) the factors that motivate the relevant constituency;

(b) the activities that an organisation seeks to encourage; and

(c) the impact that the relevant activities have on the business of the organisation.

Thus, using a simple example, if money is the motivating factor and the activity that is sought to be encouraged is patent filings, this is one incentive level. The impact or value that the relevant patent filings have on the business of an organisation is another incentive level. It is this impact layer that is frequently missing from incentive programs and it is this layer which is likely to be most relevant to an organisation’s intellectual property strategy being aligned with its business strategy. It is the right mix of these three layers that should be the goal of any incentives program, and needs to be tailored for the relevant circumstances at hand.

**Metrics**

Metrics are perhaps the most difficult part of IP management. By metrics I mean establishing meaningful, quantifiable measures of the impact of IP management on an organisation. Amongst the difficulties in seeking such metrics are firstly, that some things are not easily susceptible to measurement, e.g. where the sale of a business goes through smoothly because the intellectual property was in order or where an organisation has detected and stopped a competitor’s infringement because of a monitoring program of competitor activities. Secondly, it may not be possible to isolate one particular activity as the cause of a certain outcome, e.g. it may not only be significant to have a patented product in the market, which derives from aligning IP strategy with business strategy, but the marketing, strategy and minimisation of manufacturing costs, amongst other things, can be equally important to a product’s success in the market place. Thirdly, it can take time for an activity to have an impact and it may be difficult to determine what time should be allowed for the success or otherwise of a component of IP management to be judged.

My caution is therefore do not become obsessed by metrics, or as Professor Tim Devinney, co-author of the Australian Graduate School of Management/Freehills Report entitled “The Management of Intellectual Property in Australian Organisations” (AGSM/Freehills Report) puts it:

“...fundamentally, what you find is that the firms that are very good at IP management have an understanding that they are not going to be able to measure it perfectly and what they do is put emphasis on the processes to do it as best as they can. What we discovered in the Australian Graduate School of Management/Freehills Report is that doing it as best as your can, is a lot better than not doing it at all.”

Having said that you should not become obsessed, there are obviously some measures that may be relevant and easily identifiable, e.g. licensing income, sales revenue from patented products, cost savings in maintaining a patent or trade mark portfolio etc. It should also, however, be clearly understood there is no better way to attract the approval of an organisation’s top management than to provide it with metrics that show the positive impact that IP management is having on the drivers of that organisation.

Additionally, whilst it is easier said than done, benchmarking your organisation against comparable organisations or market leaders should be an activity that is high on the metrics agenda.

Whatever metrics you choose or, more likely, whatever metrics evolve out of your IP management, make sure that they are meaningful to your organisation’s purposes.

**Integrated/unobtrusive systems**

Irrespective of whether the appropriate metrics have been or are capable of being determined in relation to an IP management program, the more efficient the systems that form part of the program, the more likely the program will add value to an organisation. That value is more likely to arise if the systems do not impose a significant additional burden on those affected by it. Thus, where possible, they should be integrated into existing systems of an organisation, e.g. in the case of establishing an intellectual property inventory, this could be an element derived from the requirement of the accounting standards to have an inventory of intangible assets. They should also be unobtrusive in the
sense that they are or become a normal feature of an organisation’s day to day activities. This in turn results in conduct that becomes “second nature,” or “unconsciously skilled” in psychologist’s jargon.

The areas where systems are needed are as follows:

• Capture/assessment/conversion of knowledge to IP rights.
• Interaction with lawyers at the right time.
• Interaction with business units at the right time.
• Interaction with strategic planners.
• Keeping intellectual property inventory current.
• Monitoring competitors’ activities.
• Capturing and assessing information relevant to any metrics.
• Administration of IP portfolio.

In relation to the capture, assessment and conversion of knowledge to intellectual property rights, by way of example, some companies have their in-house patent attorneys physically located next to, or inside laboratories, where developments are likely to occur. Those patent attorneys interact with scientists and technical people both in formal and less formal social settings.

Interactions with lawyers at the right time, in my experience, usually stem from factors such as an appropriate intellectual property education program; lawyers being an appropriate sign off party in relation to certain activities, e.g. the development of a new trade mark; and lawyers taking part in the planning process of an organisation.

Each of the other areas mentioned by me are equally important, but in the time available, I will not have the opportunity to consider them in any greater detail.

IP Policy

An intellectual property policy can have either an inward looking component, an outward looking component, or both.

The inward looking component seeks to identify the entitlements of an organisation’s internal constituency to the ownership and use of IP rights created within that organisation, e.g. in a university context, students generally, Ph.D. students specifically, academics, both permanently employed and visiting scholars, part time staff who have appointments both at universities and at hospitals, etc. That policy will not only seek to identify such entitlements, but it will also seek to make the policy on those entitlements legally binding. Some people tend to forget, however, that the mere promulgation of a policy does not necessarily mean that it is automatically legally binding on the relevant constituency.

The outward looking component seeks to identify an organisation’s preferred means of dealing with its IP rights and with IP rights that arise from interactions with third parties. The outward looking component may be published externally or may be purely for internal consumption. An organisation needs to very carefully consider the advantages and disadvantages that publication can bring about.

Responsibility for implementation

The final element that I consider is the person responsible for implementing any IP management program. That person must have seniority and status and must, if any metrics are determined for the IP management program, have achievement of those metrics as part of his or her key performance indicators.

The preceding may be a useful checklist of issues for you to consider in developing your own IP management program.

VARIABLES

After considering the possible purposes and elements that can comprise an IP management program, one still needs to consider other variables in order to make that program relevant to your organisation. Firstly, are the activities or business being conducted by your organisation—a financial institution has very different IP needs to a beer brewing company, which in turn has very different needs to an organisation that licenses the manufacture of its beer products. Secondly, the industry in which an organisation conducts those activities or its business will also have a significant influence because of the behaviour of competitors regarding IP. Intellectual property may be viewed as important in an industry, but no one in the industry devotes any significant resources to its management. It may, on the other hand, be viewed as important and significant resources are devoted to its management. And finally, rightly or wrongly, intellectual property may not be viewed as important in an industry at all. Whether one does or does not conform with any industry norms concerning IP management, it is useful to undertake the exercise of determining what those norms (if any) are, because as a result you may be able to gain some advantage in either adopting largely conforming conduct or adopting non-conforming conduct regarding IP management. Such information could arise from informal enquiries; it could also arise from industry associations undertaking surveys of their members; it could also arise from surveys undertaken by IP based associations, with answers being categorised by industry. The above mentioned Petrush Williamson study is based on the latter approach, in that it resulted from a survey of the members of the U.S. Intellectual Property Owners Association. I am not aware that much industry association based or IP association based survey activity of the type referred to above actually occurs in Australia, but would suggest that it would be very useful tool to have in this context.

Thirdly, the jurisdiction in which an organisation conducts its activities or business will also be a significant determinant of the extent and nature of IP management. Conducting business in the U.S.A. is more likely to make IP management important than would be the case if business is being conducted in Russia, for instance.

Fourthly, the nature of the intellectual property itself will be a very
significant factor in determining the nature and extent of IP management. A patent based IP management program is very different to a trade secret based IP management program or a copyright based IP management program, and so on.

The final, but very important, variable that I briefly touch on is the culture of the organisation itself. Amongst the significant considerations in relation to culture are the approach of the leader—for instance, whether what the leader says goes or whether the relevant constituency within any organisation first has to buy in to an activity before it is truly implemented. The culture of an organisation must be carefully read and understood as part of the process of determining how best to initiate and maintain an IP management program.

The preceding milieu of components draws me to two conclusions: the first is that “one size does not fit all!” so far as IP management is concerned and secondly, is that IP management requires a range of skills in order for it to be properly implemented.

**OBSERVATIONS**

For those considering the implementation of an IP management program within their organisations, the following observations may be of some value:

- Generally speaking, IP management is probably not the most important issue for Australian organisations today, but it is likely to be more important than it is currently appreciated by most Australian organisations. Therefore the importance of IP management should not be oversold.

  - That IP management should be viewed as important for all Australian organisations that seek to conduct activities in sophisticated markets outside of Australia. I have heard too many stories of Australian businesses that attack a foreign market such as the United States and, figuratively speaking, come back with a “bloody nose” because they have not done their homework on the intellectual property landscape in the market that they are seeking to enter.

  - That IP management should be viewed as important for all organisations that are creators of knowledge and that want to benefit financially from that knowledge being used in a market place.

  - That the change in accounting standards to start in Australia from 1 January 2005 relating to intangible assets will provide a wonderful opportunity for Australian organisations to embark upon the development of IP management programs, and on a grander scale, intellectual asset management programs.

**POLICY INITIATIVES**

In a context where in the Australian Graduate School of Management/Freehills Report commented “if Australia is to develop to its full potential then the management of knowledge assets must become a high priority not just to research organisations and a few elite firms, but to the vast majority of firms throughout the country. One area where this needs to be emphasised is in the management of IP—the legally enforceable rights that create and provide protection for knowledge assets,” the following two suggested policy initiatives may assist in realising that potential sooner than would otherwise be the case.

Firstly, there needs to be a clear policy recognition by Australian governments that IP management provides the missing infrastructure between “research and development” and “commercialisation.” There are muted signs of such recognition in that, for example, the requirements of Commonwealth Government programs such as R&D Start, BIF and COMET, specifically mention the need for an IP management plan. The additional components to join the dots and complete the picture would include separate funding being provided for IP management as part of such programs, together with a much clearer statement as to why IP management, in the strategic sense discussed above, is important for commercialisation.

Secondly, that IP management should itself be identified as subject matter appropriate for a Centre of Excellence, preferably in a business school environment, where it can be separately taught and researched. Government funding for such an initiative would send a clear and resounding message that IP management should be treated as a serious and necessary discipline in backing Australia’s ability.
Patent Pools: A Solution For The Telecommunications Industry

BY DON DRINKWATER*

Abstract
This paper describes patent pools and explores the potential for additional use of patent pools in the telecommunications industry. The advantages of forming patent pools to cover standards required to implement information technology products are covered as well as advantages to patent holders and licensees of the patent pool. This paper also discusses patent pool governance and patent pool economics.

What is a Patent Pool?
Patent pools have been defined as “an agreement between two or more patent owners to license one or more of their patents to one another or third parties.” One purpose of a patent pool is to provide a means for many companies to gain access to the patent rights required to sell products into the marketplace. This can promote competition and innovation. However, in some cases patent pools have been used to monopolize a market. The Supreme Court broke up a patent pool of glass manufacturers in 1945 based upon the assertion that the patent pool allowed its members to create a monopoly and sustain high prices (Hartford-Empire Co. v. United States). For that reason, patent pools are subject to antitrust actions by the U.S. Department of Justice and care must be taken by patent pool administrators to assure that the patent pool is not unlawfully inhibiting competition.

Brief History of Patent Pools
Patent pools have existed for many years. The Sewing Machine Combination formed a patent pool in 1856. In 1917 at the request of the Honorable Franklin D. Roosevelt, then the Assistant Secretary of the Navy, an aircraft patent pool was formed so that almost all aircraft manufacturers could gain access to patents necessary to supply aircraft needed to support the U.S. military in World War I. At that time the Wright Company and the Curtiss Company held patents necessary to build aircraft. Other patent pools have played a major role in bringing important technology and products to the marketplace.

Patent Issues Affecting the Telecommunications Industry
The telecommunications industry depends upon standards for compatibility. ANSI, ITU and IEEE standards address many of the technologies required for equipment to send and receive signals with compatibility. Standards like 802.3 for Ethernet, MPEG and G.729 for data compression, and DOCSIS for modems govern how devices communicate with each other. Compliance with these standards is mandatory to market products successfully. To complicate matters further, many of these standards evolve to address improvements to the products and many products must conform to multiple standards.

A recent example is the standard to send power over an ethernet cable. IEEE802.3af describes the Power over Ethernet standard. This standard provides a means to power devices such as wireless access points, IP telephones, and security devices that are connected to an ethernet cable without using a separate cable for power. Power over Ethernet technology significantly enhances the desirability and customer attractiveness of these products even though the products can and do exist without the technology. A company that does not have access to the technology would be at a significant disadvantage in the marketplace.

In many cases, patents crowd the technologies required to implement the standard. Standards bodies generally make participants sign agreements whereby they will promise to license their patents that are essential to the standard on a non-discriminatory and reasonable basis. However, non participants are not bound by such commitments and, even if all patent holders are offering their patents essential to the standard for license, the process of negotiating multiple licenses with each patent holder can be an onerous task. Patent issues related to standards can become the subject of long lasting challenges.

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2. See Patents Pools, 5.
and expensive litigation that create a cloud of doubt for many manufacturers. The conflict between patent holders that have a right to receive fair compensation for their innovation and manufacturers that are trying to compete and to develop a marketplace for the new products creates a difficult environment for the industry.

While in many cases a few large companies own multiple patents essential to a standard, universities and individuals may also own essential patents. A disruption to technology adoption that would benefit consumers can occur due to the conflicting objectives of diverse constituencies. In some cases patent pools may provide a solution to such problems.

**The Benefits of a Patent Pool**

A patent pool benefits Licensors and Licensees in a number of ways. The following lists some of the benefits:

**For the Licensor:**
- Minimizes administration cost to license the essential patents.
- Allows licensing staff to work on other licensing efforts.
- Reduces the risk of costly litigation since the patent pool creates a shield between the Licensees and Licensors.
- Provides a means for the Licensor to license to a greater segment of the market.
- In many cases assures that the Licensor receives a grant back to the Licensee’s patents that may become essential to the standard.

**For the Licensee**
- Provides a simple means to gain rights to many, if not all, of the patents essential to build products that meet a standard.
- Minimizes legal expenses associated with negotiating and signing multiple licenses.
- Supports innovation by the Licensee since the Licensee is less likely to be stopped from practicing the standard’s technology.
- Reduces total royalty exposure that might result from patent royalty stacking. Patent royalty stacking occurs when a Licensee must take multiple licenses to produce a product and the royalties stack, becoming prohibitively expensive.
- Minimizes administration costs and provides a shield between the Licensee and Licensor in regards to royalty collection and auditing.

**For the Industry**
- Fosters competition.
- Fosters innovation, since companies are rewarded for their innovation.
- Provides a safety net for distributors against becoming involved with expensive patent litigation since they know that suppliers are licensed.

While the benefits are clear, Licensors may believe that they will achieve higher royalties if they license directly. This may be true if they have a significant organization that can institutionalize licensing programs easily. These companies may also believe that joining a patent pool and agreeing to receive effective royalty rates lower than if they license directly could diminish the value of their IP. However, these companies run the risk that they will not become part of a core of companies participating in a shared manner to gain access to evolving technology essential to new areas of the standard.

**Patent Pool Governance**

For patent pools subject to U.S. Jurisdiction, the U.S. Department of Justice and the Federal Trade Commission (“Agencies”) issued a set of guidelines for licensing intellectual property on April 6, 19954 that have relevance. Section 5.5 of this report addressed cross-licensing and pooling arrangements. The Agencies monitor such arrangements to be certain that they do not create an anti-competitive environment. Regarding patent pooling, the Agencies do not require that the pool be open to all who would like to join. However, the Agencies state that “exclusion from cross-licensing and pooling arrangements among parties that collectively possess market power may, under certain circumstances, harm competition.” The Agencies provide specific guidelines to assess whether exclusion inhibits competition.

The Agencies are also concerned that a pooling arrangement may deter or discourage innovation. This may occur if the pooling agreement requires grant back of the rights protecting innovation at nominal rates. Participants may decide that innovation is not economically justifiable under such a scenario. However, the Agencies acknowledge that innovation may be enhanced by exploiting economies of scale and complementary capabilities of the participants. Assuring participants that they will have rights to practice the technology and receive reasonable rewards is likely to encourage their investment for innovation.

The Agencies should be contacted if any competitive questions exist regarding pooling arrangements.

**Patent Pool Economics**

Patent pools provide an efficient means to license patents necessary to a standard. However, patent holders may believe that they will receive a lower royalty rate than they might otherwise if they license directly. Richard J. Gilbert5 provides a fairly vigorous analysis of the economics of patent pools. Trade-offs regarding royalty rates depend upon the number of patents in the pool and the number of companies participating in the pool. While the absolute royalty rate for a single patent may be lower, the net royalties may be greater due to the decreased cost to operate the licensing program and the potential to access licensees more easily.

---

Observations by Patent Pool Administrators

The following observations were noted during interviews with three people currently administering patent pools:

1. The pool administrator evaluates the pool based upon marketplace needs and financial hurdle rates for the administrative company.

2. The administrator looks for standards based technologies where more than four major patent holders exist.

3. An independent evaluator is selected to review patents submitted to a pool and choose those deemed to be essential to the standard.

4. The administrator forms a licensing committee made up of members from pool participants. This committee meets several times over the course of about one year to establish the terms and conditions governing the pool.

5. The administrator funds the initiation of the pool.

6. The administrator performs all licensing activities.

7. Pool membership is voluntary and pool members do not forfeit their right to license or enforce their patents independently.

8. Pool Licensees are usually required to grant back any patents that they have or obtain in the future that are essential to the standard.

Summary

Patent pools provide a structure to group multiple patents owned by multiple companies that are essential to implement a standardized technology. If implemented correctly and within regulated guidelines, a patent pool can be a very efficient mechanism to further innovation and foster a competitive marketplace.

Patent pools have existed for many years covering technologies as diverse as sewing machines and pharmaceuticals.

The telecommunications industry has benefited from patent pools and there may be a case to suggest that additional use of patent pools would reduce litigation expense and provide a healthier intellectual property environment for both patent holders and licensees.

Patent pools are subject to antitrust actions and the patent pool administrator must be certain that the patent pool adheres to certain government guidelines before implementation. While royalty rates for a specific patent may be lower, the total value of a licensing program for a Licensee could be higher due to the decreased costs to license the patents, decreased litigation exposure, and increased market penetration.

Acknowledgements

I want to acknowledge the help of Nathalie Beaudoin and Sarah Bernard of Sipro Lab Telecom for their help and guidance regarding the practical application of patent pools, and Dana St. James and Bill Becker, both from 3Com Corporation, for their editorial comments.
Valuation Of Biotechnology—Stage Of Clinical Development Is Most Important

BY JEREMY WEBSTER, TREVOR PHILIPPON & MYKHAYLO HOTSALIUK*

Complexity of Valuation of Biotechnology

Valuation of biotechnology is very complex. There are a number of factors impacting the value of biotechnology companies and their assets that are difficult to evaluate. One major question is: will this development company ever have a product that will reach the market and generate sales? Other factors impacting the valuation of biotechnology include: expected time to market, expected market size, product pricing, expected market penetration, the strength of the technology and intellectual property, presence of major pharmaceutical partners, attitudes towards certain scientific developments (e.g. stem cell research, cloning and genetically modified organisms), competitive products in development, competitive products in the market, and management strength.

The volatility of the sector adds further difficulty to the valuator’s task.

However, we have observed that when determining value, the market places significant emphasis on the stage of clinical development. In this paper we examine this hypothesis.

Stage of Clinical Development

Development of a therapeutic for the treatment of disease requires a process of obtaining regulatory approval for the sale of the drug. Each country has its own regulatory body such as the Food and Drug Administration (FDA) in the U.S. and the Health Protection Branch (HPB) in Canada.

In order for a drug to be approved for sale or use by consumers, there are several stages of clinical development. The objectives of the phases of clinical development can be summarized as shown in Table 1.

The typical costs and success rates can be summarized as shown in Table 2.

*Jeremy Webster, CA, CBV, ASA; Trevor Philippon, CA; and Mykhaylo Hotsaliuk, CA. of Deloitte & Touche Corporate Finance Canada Inc.

<table>
<thead>
<tr>
<th>Table 1. From the initial idea to the marketplace: The typical drug development &amp; approval process</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-3 Years</td>
</tr>
<tr>
<td><strong>Research</strong></td>
</tr>
<tr>
<td>Idea ▼</td>
</tr>
<tr>
<td>Target ▼</td>
</tr>
<tr>
<td>Hit ▼</td>
</tr>
<tr>
<td>Lead ▼</td>
</tr>
<tr>
<td>Candidate Drug</td>
</tr>
<tr>
<td>Laboratory &amp; animal studies</td>
</tr>
</tbody>
</table>

Source: Biochem Pharma, 1998 Annual Report
Determination of Sample of Companies

In deriving a sample of companies to evaluate our hypothesis, we used the following criteria:

1. The company is engaged in the development of a human therapeutic.
2. The company is not in financial difficulty.
3. The company’s lead therapeutic is in (or expected to launch—for preclinical companies) human clinical trials.
4. The company does not have significant revenues.

After applying the above criteria our sample contained 30 companies, (see Appendix 1).

We then segregated the companies into three groups according the stage of development of their lead therapeutic.

1. Pre-clinical and phase I
2. Phase II
3. Phase III

Calculation of Technology Value

We determined the technology value as follows:

1. We calculated the market capitalization of each of the companies as of December 31, 2001.
2. We calculated the technology value by subtracting the cash and marketable securities from the market capitalization. We used the balances from companies’ financial statements closest to December 31, 2001.

Conclusions

1. Stage of clinical development is the most important factor when determining the fair market value of biotechnology companies and their assets.
2. The stage of clinical development incorporates other major valuation drivers such as expected time to market, strength of the science and technology, management, and intellectual property. Clearly, strength in these other areas will help lead to success in the clinic.
3. The range of technology values for Canadian public therapeutic development companies at December 31, 2001 was as shown in Chart 1.

Calculation of Technology Value as of December 31, 2001

<table>
<thead>
<tr>
<th>Typical number of patients</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Submission for new drug approval</th>
<th>Phase IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timing</td>
<td>N/A</td>
<td>20-80</td>
<td>100-300</td>
<td>1,000-3,000</td>
<td>N/A</td>
<td>Varies</td>
</tr>
<tr>
<td>Cost per compound $ million</td>
<td>5.9</td>
<td>7.3</td>
<td>18.9</td>
<td>43.3</td>
<td>1.0</td>
<td>12.5</td>
</tr>
<tr>
<td>Attrition rate Number of compounds tested for each drug approved</td>
<td>10.0</td>
<td>5.0</td>
<td>3.5</td>
<td>1.5</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Total cost per approved drug $ million</td>
<td>59.0</td>
<td>36.5</td>
<td>66.2</td>
<td>65.0</td>
<td>1.0</td>
<td>12.5</td>
</tr>
</tbody>
</table>


Chart 1. Range of Technology Value by Phase of Clinical Development

Canadian Biotechnology Industry

## Appendix 1. Canadian Biotechnology Industry

### Market Value of Companies—Biotech Industry—Phase III Clinical Trials

At December 31, 2001

<table>
<thead>
<tr>
<th>Name</th>
<th>Area of Study</th>
<th>Number of Projects in Phase</th>
<th>Market Capitalization (CND$ millions)</th>
<th>Cash &amp; Cash Equivalents (CND$ millions)</th>
<th>Market Securities &amp; Short term investments (CND$ millions)</th>
<th>Technology Value (CND$ millions)</th>
<th>Most Recent Quarterly Financial Statement Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. AEterna Laboratories Inc.</td>
<td>Cancer &amp; Cosmetic Ingredients</td>
<td>1 2 2</td>
<td>$261.4</td>
<td>$26.7</td>
<td>$31.5</td>
<td>$203.2</td>
<td>9/30/2001</td>
</tr>
<tr>
<td>2. Angiotech Pharmaceuticals Inc.</td>
<td>Inflammatory Diseases and Surgical Instruments</td>
<td>6 2 1 2</td>
<td>$1,386.4</td>
<td>$3.2</td>
<td>$152.9</td>
<td>$1,230.3</td>
<td>9/30/2001</td>
</tr>
<tr>
<td>3. Biomira Inc.</td>
<td>Cancer</td>
<td>2 1</td>
<td>$348.1</td>
<td>$26.4</td>
<td>$55.5</td>
<td>$266.2</td>
<td>9/30/2001</td>
</tr>
<tr>
<td>4. Hemosol Inc.</td>
<td>Blood Substitutes, Cardiac, Cancers</td>
<td>5 2 1 1 1</td>
<td>$300.7</td>
<td>$27.4</td>
<td>$68.4</td>
<td>$204.9</td>
<td>9/30/2001</td>
</tr>
<tr>
<td>5. Inex Pharmaceutical Corp.</td>
<td>Cancer, Infectious Diseases</td>
<td>4 3 1</td>
<td>$275.3</td>
<td>$7.5</td>
<td>$26.5</td>
<td>$241.3</td>
<td>9/30/2001</td>
</tr>
<tr>
<td>6. Stressgen Biotechnologies Corp.</td>
<td>Stress Protein-Based Immunotherapeutics</td>
<td>3 1</td>
<td>$264.8</td>
<td>$1.4</td>
<td>$46.0</td>
<td>$217.4</td>
<td>9/30/2001</td>
</tr>
<tr>
<td>7. Theratechnologies Inc.</td>
<td>COPD, Hip Fractures, Cell Therapy, Immune</td>
<td>4 1 5 1</td>
<td>$369.5</td>
<td>$31.8</td>
<td>$29.0</td>
<td>$308.7</td>
<td>8/31/2001</td>
</tr>
</tbody>
</table>

### Average

| 4 2 2                                           | $458.0                             | $17.8                                  | $38.5                                                    | $381.7                                           | 9/30/2001                                       |

Notes: 1 Cash and Marketable Securities figures as per most recent quarterly financial statements
SETTLEMENT AGREEMENT GRANTS IMPLIED SUBLICENSE TO CUSTOMERS OF LICENSEE

A settlement agreement granting an affirmative right to sell components for use in infringing devices will grant an implied sublicense to customers who purchase those components for the manufacture, use, and sale of infringing devices. In *Jacobs v. Nintendo of America, Inc.*, No 03-1297 (Fed. Cir. May 28, 2004), the United States Court of Appeals for the Federal Circuit held that the grant of such an implied sublicense barred a suit for patent infringement by a patentee against a component supplier’s customer.

This case related to tilt sensitive video game controllers for which Jacobs held a patent. In a previous action, Jacobs sued several entities including Analog Devices, Inc. (“Analog”) for infringement of its patent. Specifically, Jacobs sued Analog for inducement and contributory infringement based on Analog’s supply of tilt-sensitive components to the other defendants in that action.

The case between Jacobs and Analog was resolved by a settlement agreement. As part of that agreement Jacobs granted Analog a license to “take any actions…, which would, but for [the] license, constitute an infringement” of Jacob’s patent. The agreement further stated that “the license granted hereunder includes the right to make, use, sell, import, and export” tilt-sensitive components for “use in tilt-sensitive control boxes.” Finally, the agreement also included a covenant by Jacobs not to sue Analog for any violation of his patent.

In the present case, Jacobs sued Nintendo for patent infringement based on the sale of one of its video game systems. Nintendo asserted that it was entitled to practice the patent-in-suit because the tilt-sensitive components used in the accused Nintendo devices were supplied by Analog. The District Court held that Nintendo had an implied license under Jacobs’s patent because of the agreement between Jacobs and Analog and therefore granted Nintendo’s motion for summary judgment of noninfringement.

On appeal, the Federal Circuit affirmed the holding of the district court. The court stated that the agreement between Jacobs and Analog “makes sense only if it is understood to confer on Analog the right to make and sell [tilt-sensitive components] for use in tilt-sensitive control boxes that would otherwise infringe Jacob’s rights.”

The Federal Circuit held that this clause barred Jacobs from prohibiting Analog’s customers from making, using, and selling control boxes with those components. In the court’s view, to hold otherwise would run afoul of the basic contract principle that a party may not assign a right, receive consideration for it, and then take steps to render that right worthless.

Moreover, the Federal Circuit found that in light of the other provisions of the agreement, it would be incorrect to interpret the provision as granting only a bare license to Analog. Such an interpretation would ignore the language of the agreement that went beyond the creation of the license and granted the right to make and sell components for use in tilt-sensitive control boxes. It would also render the covenant not to sue redundant. Therefore, the Federal Circuit found that the agreement granted Analog’s customers an implied sublicense to use Analog’s components to make, use, and sell tilt-sensitive control boxes that infringe Jacobs’s patent.

SETTLEMENT AGREEMENT DOES NOT RELEASE THIRD PARTY WHO ACQUIRES LICENSEE AFTER EXECUTION OF THE AGREEMENT

A settlement agreement releasing a licensee and its parents from claims of infringement will not provide a release to a third party who later becomes the licensee’s parent. In *Unova, Inc. v. Acer Inc.*, No. 03-1244, (Fed. Cir. March 31, 2004), the United States Court of Appeals for the Federal Circuit held that a settlement agreement between Unova and Compaq did not provide a release to Hewlett-Packard after Hewlett-Packard purchased Compaq.

This case related to smart battery patents held by Unova. Prior to the present case, Unova and Compaq entered into a settlement agreement whereby Unova released Compaq and its “parents” from liability for infringement. The agreement further provided that Unova would not sue Compaq or its parents for infringement by any “Compaq Products” and granted a non-exclusive license to Compaq and its parents under the smart battery patents.

Almost a year after the agreement was signed, Hewlett-Packard purchased all of the stock of Compaq, thus be-
coming Compaq’s parent. Subsequently, Unova sued Hewlett-Packard for patent infringement. Hewlett-Packard moved for summary judgment that the agreement between Unova and Compaq released Hewlett-Packard from liability for infringement of the smart battery patents. The District Court granted the motion, and Unova appealed.

The Federal Circuit held that the District Court erred in granting Hewlett-Packard’s motion for summary judgment. The court held that under California contract law, a third party’s rights under a release agreement are predicated upon the contracting parties’ intent to benefit that third party. The Federal Circuit held that Unova and Compaq did not intend to release Hewlett-Packard from liability for infringement arising from events that occurred before it became Compaq’s parent. According to the court, the agreement intended only to release Compaq and its parents as of the date the agreement was signed. Since Hewlett-Packard became Compaq’s parent later, it was not covered by the release.

The Federal Circuit also noted that this interpretation was consistent with the other provisions of the agreement. Notably, the covenant not to sue and license provisions applied only to Compaq-branded products. The court noted that it would be unusual for the agreement to release Hewlett-Packard for past liability but reserve the right to sue Hewlett-Packard for identical acts of infringement that occurred after it became Compaq’s parent. Therefore, the Federal Circuit reversed the decision of the District Court.

**PATENTEE CANNOT RECOVER LOST PROFITS OF A SISTER CORPORATION IN A PATENT INFRINGEMENT ACTION**

If a parent corporation creates two subsidiaries, one that holds its patent rights and one that makes the patented product, the patent-holding subsidiary will not be able to recover the lost profits of the manufacturing subsidiary. In *Poly-America, L.P. v. GSE Lining Technology, Inc.*, No. 04-1022, (Fed. Cir. September 14, 2004), the United States Court of Appeals for the Federal Circuit held that Poly-America was not entitled to lost-profits damages of its sister corporation despite the close relationship between the two companies.

This case involved patents relating to textured landfill liners owned by Poly-America. Poly-America sued GSE lining for patent infringement and a jury found in favor of Poly-America and awarded Poly-America a reason-able royalty and lost-profits. Poly-America did not actually manufacture the patented product. Rather, its sister corporation Poly-Flex did. Poly-Flex operated under a non-exclusive license under the patents and had granted Poly-America the right to collect damages on its behalf. Therefore, the lost profits awarded by the jury were based on the lost profits of Poly-Flex, not Poly-America.

The Federal Circuit held that Poly-America was not entitled to recover Poly-Flex’s lost profits. The Court held that while Poly-America and Poly-Flex seem to share interests as two entities collaborating in the manufacture and sale of textured landfill liners, that relationship was not sufficient to permit Poly-America to claim Poly-Flex’s lost profits. The Federal Circuit found that since their parent corporation set up the companies as separate corporate entities, it must take the benefits of that structure with the burdens. Therefore, even though Poly-America had the right to sue under its patents, it can only recover its own lost profits, not Poly-Flex’s.

Moreover, the fact that Poly-Flex granted Poly-America its right to collect damages did not alter the decision. Since Poly-Flex was only a non-exclusive licensee, it could not sue for damages on its own. Therefore, Poly-Flex had no right to collect lost profits. Therefore, the Federal Circuit reversed the award of lost profits to Poly-America.

**JAPANESE FTC FINDS MICROSOFT’S LICENSING POLICY IN VIOLATION OF ANTIMONOPOLY ACT**

On July 13, 2004, the Japanese Fair Trade Commission (“JFTC”) issued a recommendation to Microsoft concluding that certain provisions in Microsoft’s Windows operating system (“OS”) licenses violated the Antimonopoly Act. The contracts at issue were license agreements entered into with PC manufacturers who wished to place the Windows OS on their computers. The agreements required the PC manufacturers to agree not to sue Microsoft for any infringement of the PC manufacturer’s patents by the Windows OS. The JFTC found that these non-assertion provisions unjustly restricted the business activities of the PC manufacturers.

The JFTC noted that Microsoft has a dominant position in the PC market and that it is extremely important to the PC manufacturers to obtain licenses to each new version of the Windows OS as it becomes available. The JFTC further noted that Microsoft has increasingly incorporated audio and visual functions (“AV function”) into its Windows OS and that many PC manufacturers were also developing technologies and held patents relating to AV function. The commission found that when PC manufacturers objected to waiving their right to assert their AV function patents against Microsoft, Microsoft refused to alter the agreement, thereby forcing the PC manufacturers to accept the provision.

The JFTC found that this licensing practice restrained PC manufacturers from enforcing their patent rights. The JFTC further found that such a restraint might cause these manufacturers to lose their incentives to invent and develop technology related to AV function. Therefore, the commission found that Microsoft violated the Antimonopoly Act. The JFTC concluded by recommending that Microsoft remove all such provisions from its current agreements, and further agree not to include such provisions in future agreements.

In response, Microsoft has publicly decided to no longer include such provisions in its future agreements. Microsoft, however, rejected the JFTC’s recommendation and instead chose to proceed with a hearing on its licenses. At present, this matter is still pending.
PATENTEE ENTITLED TO LOST PROFITS ON SALES OF UNPATENTED MATERIALS SOLD WITH A PATENTED DEVICE

A patentee may recover its lost profits from lost sales of unpatented materials it sells with a patented device if it can demonstrate a functional relationship between the device and materials. In Juicy Whip, Inc. v. Orange Bang, Inc., No. 03-1609, (Fed. Cir. September 3, 2004), the United States Court of Appeals for the Federal Circuit held that Juicy Whip was entitled to present evidence on its lost profits on lost syrup sales due to Orange Bang’s infringement of its beverage dispenser patent.

Before the district court, a jury found that Orange Bang infringed Juicy Whip’s beverage dispenser patent and awarded Juicy Whip compensatory damages. At trial, Juicy Whip sought to introduce evidence on its lost profits on syrup sales, but the district court denied Juicy Whip’s motion because it did not believe the syrup and patented dispenser constituted a single functional unit.

The Federal Circuit found that the district court abused its discretion by not allowing Juicy Whip to present evidence of lost profits on syrup sales. The court held that the appropriate test for determining whether a patentee could recover lost profits on sales of unpatented materials was whether the unpatented materials have a functional relationship with the patented device. The Federal Circuit found that the syrup and beverage dispenser shared a functional relationship and were analogous to parts of a single assembly. Specifically, the syrup functioned together with the dispenser to provide a visual appearance that was central to the patent. Moreover, the fact that other syrups could be used with the dispenser did not alter this result. Therefore, the Federal Circuit vacated the jury’s damage award and remanded for further proceedings on the issue.

SUPPLYING INSTRUCTIONS OR CORPORATE OVERSIGHT FROM THE UNITED STATES FOR PRODUCTS MADE OUTSIDE THE UNITED STATES DOES NOT CONSTITUTE INFRINGEMENT

A company that manufactures and sells an accused product entirely outside of the United States typically is not liable for patent infringement. However, the U.S. patent law also provides that someone who supplies a substantial portion of components of a patented invention from the United States for combination outside of the United States is liable for patent infringement in the United States. In Pellegrini v. Analog Devices, Inc., No. 04-1054, (Fed. Cir. July 8, 2004), the United States Court of Appeals for the Federal Circuit held, on a case of first impression, that components that are manufactured outside the United States and never physically shipped to or from the United States, do not infringe a U.S. patent even if those components are designed within the United States and the instructions for their manufacture and disposition are transmitted from within the United States.

This case involved chips manufactured by Analog Devices outside of the United States that were never physically shipped to or from the United States. Analog Devices did, however, design the chips in the United States and provided the instructions for their manufacture from within the United States. Pellegrini asserted that Analog Devices was liable for infringement under section 271(f) of the U.S. patent laws. Section 271(f) provides liability for a company who supplies all or a substantial portion of the components of a patented invention from the United States for combination outside of the United States. The district court had granted Analog Devices motion for summary judgment that section 271(f) did not apply to its activities, and Pellegrini appealed.

The Federal Circuit held that section 271(f) did not apply to the activities of Analog Devices. According to the court, this section applies only when components of a patented invention are physically present in the United States and then sold or supplied outside of the United States for combination. Therefore, the fact that Analog Devices provides instructions from the United States does not create any liability for infringement since the components were not actually supplied in or from the United States.

Pellegrini pointed to the fact that the invoices shipped with all Analog Devices’ products included a statement that the “commodities, technology, or software were exported from the United States.” Pellegrini contended that even if the components were not actually shipped from the United States, the components should be deemed to have originated from the United States by virtue of this declaration. Analog Devices responded by stating that these statements were included out of an abundance of caution to comply with U.S. export laws. The Federal Circuit rejected Pellegrini’s argument noting that Analog Devices’ statements could not override the fact that no products were actually exported from the United States.

Therefore, the Federal Circuit affirmed the decision of the district court granting Analog Devices’ motion for summary judgment.
The nomination of Neelie Kroes as the new Competition Commissioner bodes well for the continued independence of DG Competition

New Commission President José Durão Barroso announced the proposed portfolios of his new team of 25 Commissioner-designates in August, but subsequently took the unprecedented step of withdrawing his team, when it became clear that he would not obtain the required endorsement of the European Parliament. President Barroso has now reconstituted his team and will seek the Parliament’s endorsement during the first half of November. Once formally appointed, he and his Commissioners will take up their posts for a term of five years.

In August, the nomination of Dutch Neelie Kroes, 63, to the Competition portfolio was unexpected. Prior to Commission President Barroso’s announcement, candidates from the UK, Greece and Ireland had been tipped for the post. Ms. Kroes has, however, attracted much praise from commentators and, notwithstanding the European Parliament and Commission legal service’s concerns about her possibly conflicting business interests, her nomination was confirmed after President Barroso’s reshuffle.

Ms. Kroes has been labelled a tough negotiator with a wide network of contacts in the international political and commercial world. Former Competition Commissioner Karel Van Miert has described her as “pragmatic, energetic and determined.” Members of the business community and their advisers consider her to be a welcome breath of fresh air, likely to be less inclined to be a stickler for the rules and more receptive to the sound commercial arguments of businesses than some of her predecessors.

In the proposed new structure, Ms. Kroes will be able to retain the freedom of manoeuvre enjoyed by outgoing Commissioner Mario Monti, who pushed through the most radical legislative and policy reforms in the 40-year life of the EC competition regime, spanning the merger, antitrust and state aid fields. No doubt the Commission’s high-profile court defeats in Airtours, Tetra Laval and Schneider during a four-month period in 2002 were a catalyst for some of the reforms in the merger field, but the outgoing Commissioner’s determination to modernise, in particular the state aid rules, should not be overlooked. As recently highlighted by Commissioner Monti himself, moreover, one of his greatest victories went wholly unnoticed by the public: he warded off pressure to introduce the co-decision procedure into legislative decision-making in the competition field.
which would have given the European Parliament power to amend or veto proposals.

The major challenges for Ms. Kroes will be bedding down the Monti reforms and tackling reform of the law on dominant companies, an area of sharp divergence between the EU and U.S. One of her most difficult tasks will be to oversee the process of decentralising the control of cartels and anticompetitive behaviour to the Member States. This will involve finding a delicate balance between the roles of the European Commission and the national competition authorities, now linked by the European Competition Network. Ms. Kroes’ background in economics is likely to continue the drive for greater economic rigour in decision-making, while her reputation for “free market” political beliefs should ensure a robust enforcement policy.

Before President Barroso’s reshuffle, Ms. Kroes had almost finalised the appointments to her private office, with Dutch Ben Smulders heading the team. Ben Smulders is a Dutch lawyer who left private practice to join the Commission’s legal service. He later served in the private offices of Hans Van den Broeck, Frits Bolkestein and President Prodi and most recently has been a member of the experts’ group debating changes to the ECJ’s structure and jurisdiction culminating in the Constitutional Treaty. Unusually, Ms. Kroes’ private office appointees all hail from within the Commission and represent six different nationalities.
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<tr>
<th>Chairs</th>
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</tr>
</thead>
<tbody>
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<td><strong>Heinz Goddar</strong></td>
</tr>
<tr>
<td><strong>Awards</strong></td>
<td>Patricia A.O. Bunye</td>
</tr>
<tr>
<td><strong>Communications</strong></td>
<td>Panos Malamis</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td>Shoichi Okuyama</td>
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<tr>
<td><strong>Endowment</strong></td>
<td>Elisabeth Thoreut-Lemaître</td>
</tr>
<tr>
<td><strong>Investment</strong></td>
<td>Christopher Liebscher</td>
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<td>Antonio Tavira</td>
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<td><strong>Chair</strong></td>
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LESI Operating Committees

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<tr>
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<tbody>
<tr>
<td><strong>Auditor</strong></td>
<td><strong>Heinz Goddar</strong></td>
</tr>
<tr>
<td><strong>Awards</strong></td>
<td>Patricia A.O. Bunye</td>
</tr>
<tr>
<td><strong>Communications</strong></td>
<td>Panos Malamis</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td>Shoichi Okuyama</td>
</tr>
<tr>
<td><strong>Endowment</strong></td>
<td>Elisabeth Thoreut-Lemaître</td>
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<tr>
<td><strong>Investment</strong></td>
<td>Christopher Liebscher</td>
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<tr>
<td><strong>IP Maintenance</strong></td>
<td>Antonio Tavira</td>
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<tr>
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For more information on LES or LESI Meetings call +1-703-836-3106 or go to www.usa-canada.les.org

2005

January 28

Benelux Topic Meeting

Brussels

February 3-5

AUTM Annual Meeting

Scottsdale, Arizona

February 9-11

Winter Meeting

Brown Palace Hotel

Denver, CO

March (Date TBD)

PDS Fundamentals & Intermediate Intellectual Asset Courses

San Francisco, CA

April 13

LES Foundation Dinner

Four Seasons Hotel

Chicago, IL

May 4-6

Spring Meeting

Sheraton Imperial Hotel

Durham, NC

June 2-3

Technology Transfer Seminar

Toronto, Canada

June 10-16

LES International Delegates and Committee Meetings

LES Annual Meeting

Arabella Sheraton Hotel

Munich, Germany

July 11-14

PDS Fundamentals & Intermediate Intellectual Asset Courses

Chicago, IL

September (Date TBD)

PDS Fundamentals & Intermediate Intellectual Asset Courses

Chicago, IL

2006

February 9-11

AUTM Annual Meeting

Orlando, FL

June

LES International Annual Conference

Seoul, Korea

June

LES International Delegates and Committee Meetings

Seoul, Korea

September 10-14

LES (USA & Canada) Annual Meeting

Marriott Marquis

New York, NY

October 8-12

AIPPI World Congress

Gothenburg, Sweden

2007

March 1-3

AUTM Annual Meeting

San Francisco, CA

June 15-17

LES International Annual Conference

Zurich, Switzerland

June 18-20

LES International Delegates and Committee Meetings

Zurich, Switzerland

October 16-19

LES (USA & Canada) Annual Meeting

Marriott Desert Ridge Hotel

Phoenix, AZ

October 20-22

LES International Delegates and Committee Meetings

LES Annual Meeting

Phoenix, AZ

November (Date TBD)

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