Patent Term Considerations in Technology Licensing at the National Cancer Institute

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Patent protection provides an incentive for companies to develop and sell products based on government and university technologies. The cost of bringing a single drug to market can be as high as $1 billion. In order to recoup this investment, companies require temporary market protection afforded to them by patents. Longer patent terms provide increased revenues. Prior to marketing, the average time from the beginning of clinical trials to marketing approval is approximately 7 years. When considering whether to license and develop technologies, patent life is therefore an important factor for industry. In order to understand the influence of patent term on licensing, technologies from the National Cancer Institute were analyzed. This study indicates that technology licensing predominantly occurs with more than 10 years of patent life remaining. This information provides a useful guide for efficient utilization of organizational resources.

INTRODUCTION

Technology transfer offices (TTO) must make important decisions that impact the allocation of organizational resources. The TTO staff has a limited amount of time available to devote to patenting, licensing, marketing and other duties. TTO activities are also limited by budgetary considerations. Decisions about which technologies merit investment of these resources are based on multiple factors. These include the novelty of the technology, inventor interest in its development and commercial interest. Resources must be committed to a technology throughout its lifespan which could include ongoing collaborative and licensing agreements as well as continued patent prosecution and maintenance. Presented here is a summary of the portion of patent lifetime that has encompassed active licensing activity for inventions at the National Cancer Institute of the National Institutes of Health, Department of Health and Human Services.

Summary of Commercialized Products with an NCI Contribution

AIDS test kits
- Tests for serum antibodies to HIV

Cervarix®
- Vaccine against Human Papilloma Virus (HPV), protects against cervical cancer

Fludara®
- Chemotherapeutic treatment for B-cell chronic lymphocytic leukemia (CLL)

Gardasil®
- Vaccine against Human Papilloma Virus (HPV), protects against cervical cancer

HIVID®
- Dideoxy cytidine (ddC) for the treatment of HIV infection

IL-2 receptor
- Reagent used in immunology and cancer research

Kepivance®
- Keratinocyte Growth Factor (KGF) for treatment of severe oral mucositis in patients with hematologic malignancies undergoing chemotherapy treatment

Layered Peptide Arrays
- Analysis of cancer fingerprints using layered protein expression scanning

Monoclonal antibodies to P450 enzymes
- Antibodies used for drug toxicity studies

NeuTrexin®
- Small molecule inhibitor of dihydrofolate reductase (DHFR) for treatment of Pneumocystis Carinii pneumonia in immuno-compromised patients

PathVysion® HER-2 DNA probe kit
- Fluorescence In Situ DNA hybridization for detection of HER2/neu gene amplification in breast cancer tissue

Pathway® HER-2 protein detection
- Detection of HER-2 positive breast cancer tissue

PhenoSense™ HIV phenotype tests
- Diagnostic for determining drug resistance of HIV strains

PixCell® Laser Capture Microdissection system (LCM)

- Enables harvesting single cells or tens of thousands of cells for analysis from tissue samples in a few seconds using a laser

PPARα-deficient mice

- Used for development of drugs for treatment of type 2 diabetes and lipid disorders

Prezista®

- Small molecule HIV protease inhibitor

Select100™

- Automated delivery of multiple specimens into an electron microscope

Squirrel-free capsaicin-treated birdseed

- Birdseed not eaten by squirrels

Taxol®

- A method for using Taxol® in cancer treatment

TGF beta

- Reagent used in immunology and cancer research

Velcade®

- A small molecule proteosome inhibitor to treat multiple myeloma

Videx®

- Delayed release capsules of didanosine (ddI): a Reverse Transcriptase inhibitor for HIV infection

Vitravene®

- Phosphorothioate anti-sense oligonucleotide to treat CMV infection of patients with AIDS

Zevalin®

- Radio-labelled anti-CD20 mAb for treatment of non-Hodgkin's B-cell lymphoma in conjunction with another anti-CD20 mAb (Rituxan®)

METHODS

Time from patent priority date to licensing for each license was calculated as follows. Time of licensing is the effective date of a license upon initiation of a new license agreement. Where multiple technologies are included in an agreement, the technology that had the shortest amount of time between the priority date and the license effective date was used. Only patents that have priority dates on or after June 8, 1995 are included. Data represent 261 licenses and 234 inventions. Numbers of licenses by license type are:

BIOLOGICAL MATERIAL-COMMERCIAL	3
BIOLOGICAL MATERIAL-INTERNAL USE	7
COMMERCIAL EVALUATION	57
PATENT-COMMERCIAL	159
PATENT-INTERNAL USE	28
SETTLEMENT-INFRINGEMENT	1
SETTLEMENT-INTERFERENCE	5
SETTLEMENT-LITIGATION	1

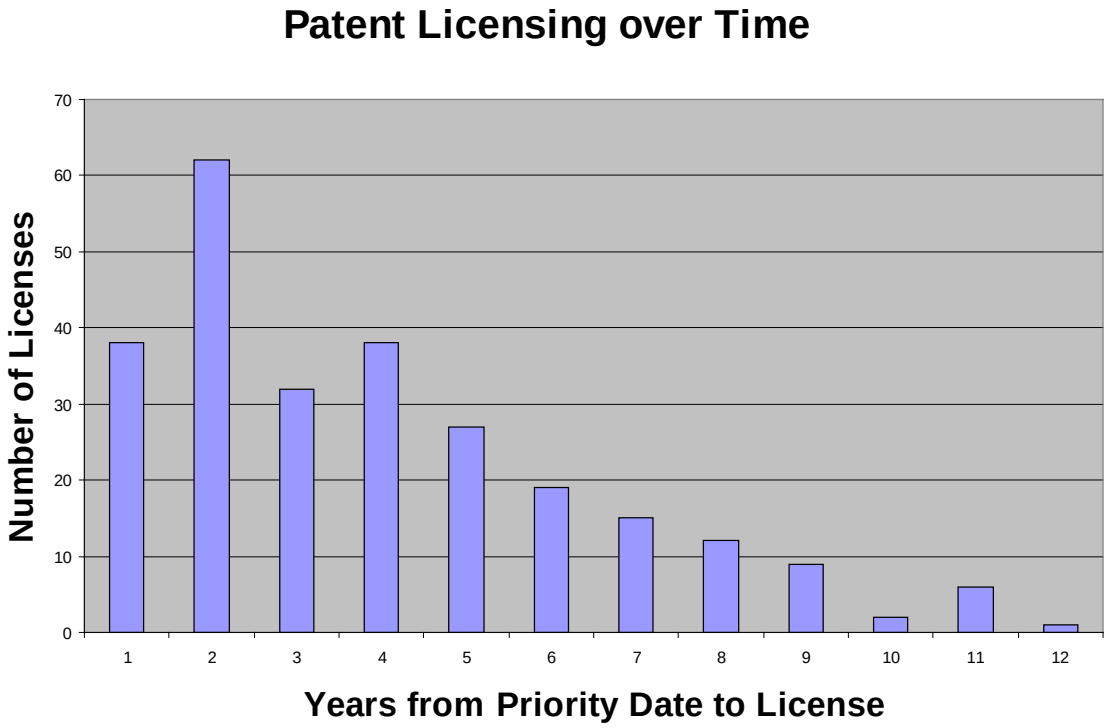
Patent Licensing over Time
Number of Licenses
70
60
50
40
30
20
10
0
1
2
3
4
5
6
7
8
9
10
11
12
Years from Priority Date to License

Figure 1

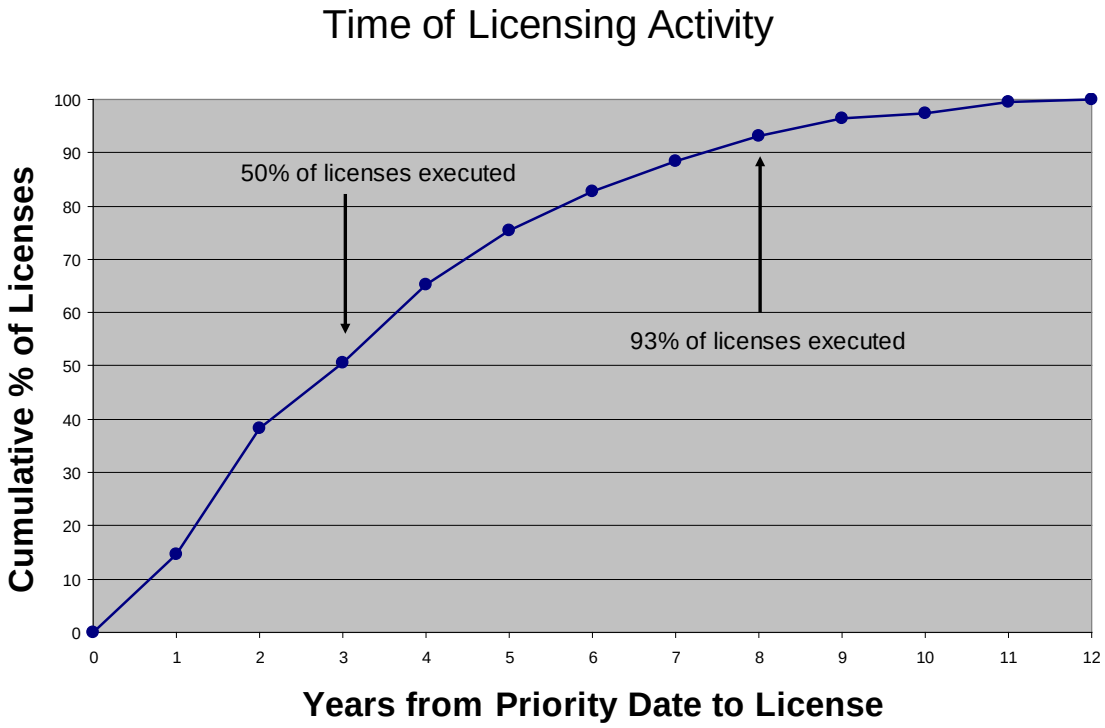
Time of Licensing Activity
Cumulative % of Licenses
100
90
80
70
60
50
40
30
20
10
0
50% of licenses executed
93% of licenses executed
0
1
2
3
4
5
6
7
8
9
10
11
12
Years from Priority Date to License

Figure 2

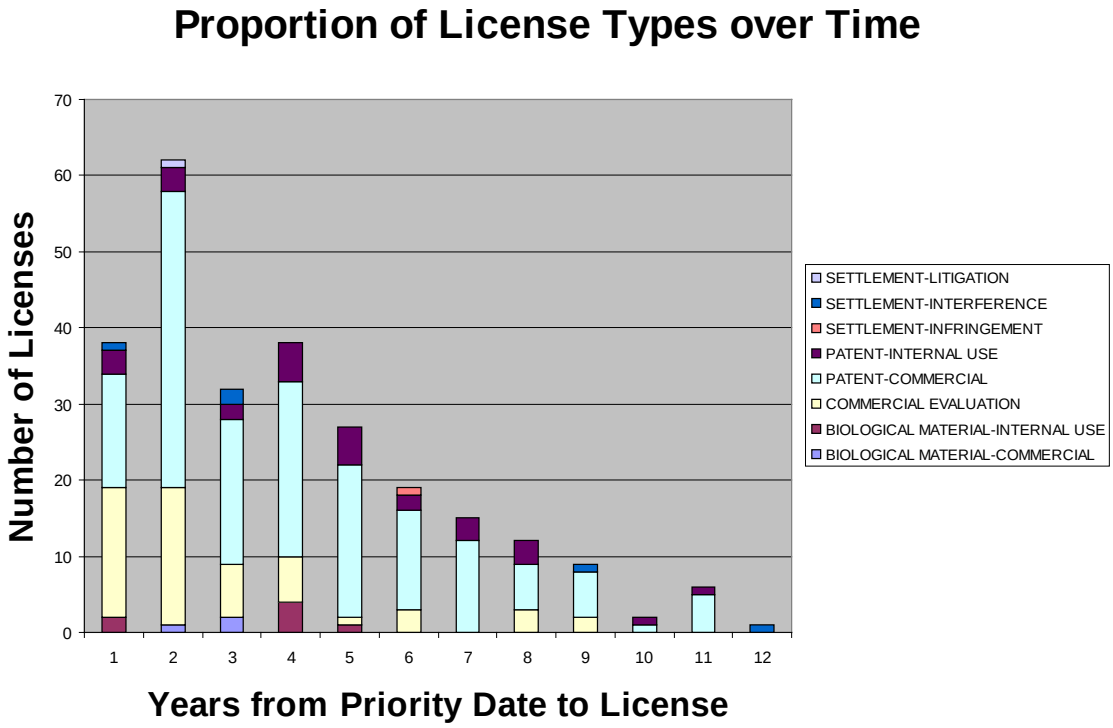
Proportion of License Types over Time
Number of Licenses
70
60
50
40
30
20
10
0
1
2
3
4
5
6
7
8
9
10
11
12
Years from Priority Date to License
SETTLEMENT-LITIGATION
SETTLEMENT-INTERFERENCE
SETTLEMENT-INFRINGEMENT
PATENT-INTERNAL USE
PATENT-COMMERCIAL
COMMERCIAL EVALUATION
BIOLOGICAL MATERIAL-INTERNAL USE
BIOLOGICAL MATERIAL-COMMERCIAL

Figure 3

DISCUSSION

A major consideration for technology transfer offices is how long organizational resources should be committed to a technology once the decision to file a patent has been made. Here we have presented quantitative data about the amount of licensing activity that occurs relative to the number of years after a patent priority application has been filed. The data indicate that only 50% of licenses are executed within 3 years after the patent priority date. Thus, in order to maximize the potential licensing and commercialization of inventions, it may be necessary for a TTO to consider maintaining patent protection of unlicensed patent applications beyond the statutory deadline for national phase filings. Conversely, 93% of licenses are executed within 8 years of the patent priority date. Thus maintenance of patent protection for longer periods may not yield additional licenses. The decline in licensing activity may be due to a number of factors including the limited remaining patent term which significantly reduces the incentive for the licensee. These data provide a useful time-frame when patent prosecution and maintenance can reasonably be considered, particularly for early-stage FDA regulated biomedical technologies such as those developed at the National Cancer Institute. However, other factors such as state of the technology, continued development by the inventor and market factors should be taken into account when making decisions about commitment of resources to patenting of individual technologies.