Office of Technology Licensing
Intellectual property newsletter
St. Jude Children's Research Hospital
ALSAC • Danny Thomas, Founder
2010 Issue

ALK Technology Used to Identify and Develop a Drug for Treatment of Non Small Cell Lung Cancer

St. Jude receives milestone payment from Pfizer

When St. Jude researchers make a discovery that has the potential to improve the lives of patients outside of our mission, the Office of Technology Licensing (OTL) gets involved to help realize that potential. This was the case in the early 1990s when Drs. Stephan Morris and Thomas Look found that many chromosomal translocations associated with anaplastic large-cell lymphomas (ALCL) involved fusions between the previously unknown Anaplastic Lymphoma Kinase (ALK) gene and a variety of other genes. These fusions cause an increase in ALK activity which is now recognized as a primary driver of cancer development.

St. Jude filed patent applications claiming ALK DNA, protein and antibody, as well as methods for detecting ALK chromosomal rearrangements and identifying compounds that inhibit the activity of ALK fusion proteins. These applications have matured into five granted patents in the US and one granted patent in Australia and Europe.

Pfizer obtained a non-exclusive license in 2002 to use these patent rights to identify and develop drugs that modulate the ALK receptor. This led to the successful development of an ALK inhibitor over the course of several years. Initiation of a Phase III clinical trial with this inhibitor to treat non small cell lung cancer (NSCLC) last fall triggered a milestone payment, which St. Jude received in March of this year. A second milestone payment will become due if and when Pfizer files a new drug application (NDA) with the FDA. The clinical experience with the Pfizer ALK inhibitor has demonstrated marked antitumor responses in patients with ALK-expressing NSCLCs, including complete tumor regressions in occasional patients. By contrast, such patients have only minimal, if any, responses to other commonly used treatments for lung cancer.

In addition to Pfizer, these patent rights are licensed on a non-exclusive basis to other companies for various uses. For example, several companies, including Life Technologies, Upstate and Dako, have a license to sell ALK antibodies for research purposes. Abbott Labs has a license to sell diagnostic kits and assays that detect ALK chromosomal rearrangements.

Morris said "It is heartening to see such practical benefits for actual patient care occur as a consequence of our studies – this represents a textbook example of translating basic research discoveries to improve clinical cancer treatment, including the therapy of malignancies such as NSCLC that are not even observed in the pediatric population seen at St. Jude." In addition, however, Morris indicated that the Pfizer inhibitor is also being testing in childhood malignancies that involve ALK mutations such as ALCL, neuroblastoma and others, and that initial results from this clinical testing should be available sometime in 2011.

The ALK story is an excellent example of how promising technology at St. Jude can be shared with commercial partners and developed into products that benefit patients beyond our target pediatric population. NSCLC is not a childhood disease and St. Jude would never have expended resources to develop a drug directed at this indication. Patenting the inventions that came from this research provided a way to get this technology into the hands of companies for further development and for St. Jude to be recognized and receive compensation for the contributions made by its scientists to this effort.

Office of Technology Licensing Satisfaction Survey

Over the summer, the Office of Technology Licensing (OTL) developed and implemented an anonymous nine question survey to gauge faculty and staff's satisfaction with the services we provide. Faculty members, postdoctoral fellows, graduate students and research technicians received email invitations to participate in the survey. The response rate was good for this type of survey, with fifteen percent of those invited to participate responding. The response rate for faculty was even better, with 27% (56 out of 204) of faculty members responding.

Overall Satisfaction/Patenting, Marketing and Handling Agreements

The OTL serves only a small portion of the total St. Jude employees involved in research according to this survey and departmental data. This is typical of most, if not all, academic technology licensing offices. Those survey respondents who had interacted with the OTL were highly satisfied with the services provided. Overall, the OTL received high marks in all categories surveyed. After excluding those who indicated they had not dealt with the OTL on the following matters, the OTL was ranked as very effective by 78% for evaluating inventions for patentability, 62% for evaluating inventions for commercial value, 53% for marketing inventions, 75% for negotiating a license, 78% for conveying consulting policies, and 91% for negotiating MTAs, CDAs and SRAs. The OTL received high ratings by over 80% of the total respondents for accessibility, responsiveness and fairness. It received high ratings by over 60% for creative problem solving and achieving results.

Most of the interactions with the OTL involve material transfer agreements. Dealing with agreements is a common source of frustration among researchers, which makes the high scores given to the OTL for effectively handling these agreements particularly satisfying.

Allocations

Of the respondents who had received an allocation from the OTL, 83% were satisfied with the timeliness of the allocation and 72% were satisfied with the information provided with the allocation.

Communications

The survey showed the OTL has room to improve its effectiveness in communicating its services with the staff. In 2005 the OTL began publishing a biannual newsletter directed toward St. Jude faculty and staff that highlights various inventions that have come out of St. Jude and provides information about the department. Although notifications went out in St. Jude Today to all employees at the time each issue was published, 80% of the respondents have never read this publication. Likewise, 86% of the respondents have never used the intranet training module and 65% have not visited our intranet website. As a result of this survey we have decided to de-emphasize our newsletter by publishing it only once a year. We now intend to take fuller advantage of the more widely read St. Jude Today and Insider by including more articles in these publications.

OTL FY2010 Activities

A summary of the OTL activities over the last four years is shown in Figures 1, 2 and 3 and a list of patents issued to St. Jude in FY2010 is found in Table 1. Figure 1 shows the number of invention disclosures received in FY 2010 dropped by 16% and licenses executed decreased by 20% from the previous year. Licensing income from St. Jude's intellectual property portfolio remained steady while patent expenses were significantly reduced, resulting in a substantial increase in net income retained for further research. In FY2010, St. Jude distributed over $900K to 77 different inventors (data not shown). The number of patent applications filed and patents issued has remained relatively stable over the past 4 years.

Figures 2 and 3 contain data related to other agreements managed by the OTL. The number of corporate research agreements fell by 70% while the number of interinstitutional, confidentiality and consulting agreement remained stable. With a decrease in the number of outgoing MTAs, the overall number of MTAs executed decreased over the last 3 years. However, the number of incoming MTAs, which can be time consuming to negotiate, steadily increased over the last 4 years.

Figure 2 shows the OTL completed 13 other agreements in FY2010 that do not fall into the listed categories. Examples of agreements that fall within this category are evaluation agreements, service agreements, dispute settlements, data transfer agreements and leases for laboratory equipment.

Figure 1.

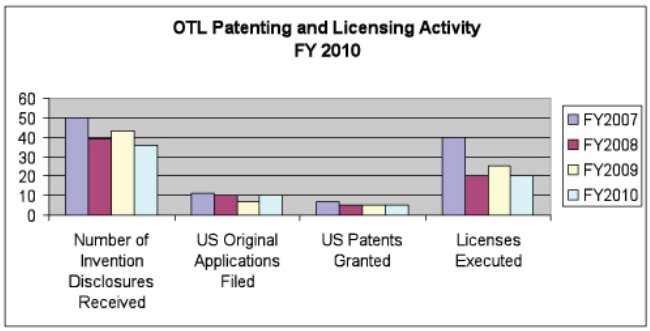

Figure 2.

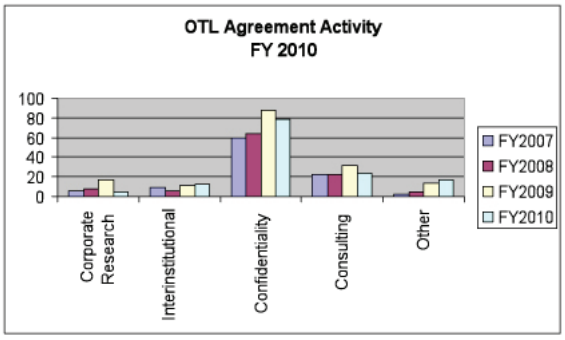

Figure 3.

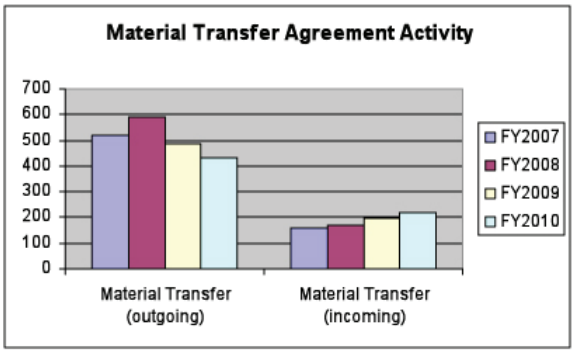

Table 1.

Patent #	Issue Date	Subject Matter	Inventor(s)
7,588,773	09/15/09	Methods and Compositions for Diagnosing and Preventing a Group B Streptococcal Infection	Elisabeth Adderson John Bohnsac Jeannine Brady Kyle Seifert
7,662,557	11/24/09	Antibodies Having Binding Specificity for the Extracellular Domain of a Breast Cancer Resistance Protein (BCRP)	Kevin Bunting Nakauchi John Schuetz Brian Sorrentino
7,645, 577	01/12/10	Group B Streptococcus Polypeptides Nucleic Acids and Therapeutics Compositions and Vaccines Thereof	Elisabeth Adderson John Bohnsack
7,704,703	04/27/10	ARF and HDM2 Interaction Domains and Method of Use Thereof	Brian Bothner Richard Kriwacki William Lewis
7,741,032	02/22/10	Genotyping Assay to Predict Gamma Glutamyl Hydrolase (GGH) Activity	Qing Cheng William Evans Mary Relling