

Knowhow + Patents that enable FTO

By
Pallavi Joshi

Taxol- A case study: From Bark to Business

- During 1960's, National cancer institute (NCI) scientists while screening for the potential chemotherapy candidates, discovered antitumor activity in bark extract from *Taxus brevifolia* (slow- growing Pacific yew tree).
- The bioactive ingredient in the bark extract, (which was later isolated and named as 'Taxol'), a mitotic inhibitor, showed a very high efficacy in treating cancer, hence was a good potential chemotherapeutic agent.
- Based on early animal tests performed, the NCI decided to proceed with human trials in 1984. However, one of the ongoing problems with Taxol was that it was only available by extracting it from the bark of the Pacific Yew tree and took **1200 kg of bark to make 10 g of Taxol.**
- NCI officials roughly estimated that if Taxol is to be made available to all ovarian cancer victims in the U.S. that year, the NCI would have to come up with roughly 240 pounds of the drug. This would require the death of 360,000 trees.

Florida State University found a moneymaking machine: The popular anticancer drug Taxol.

- Robert A. Holton, chemistry professor at Florida State University (FSU) developed an alternative synthetic pathway to produce Taxol.
- **Patented the improved process** in 1989 -1992 known as the metal alkoxide process
 - starting material was 10-deacetylbaccatin III, a taxol relative, which is relatively more abundant and is found in the needles and twigs of common English yew, which could be harvested without killing the tree.



Licensing Agreements

- In 1990, Florida State University, signed a licensing agreement with Bristol-Myers Squibb (BMS) company, giving the company the right to use the process. The Food & Drug Administration approved the semi-synthesized drug for marketing in 1994.
- Bristol-Myers Squibb was handed **an exclusive licensing agreement @ 4.2% royalty**, to use Holton's spanking new semi-synthesis patent plus any related patents that his research might cook up over the next five years.
- In exchange, FSU was entitled to royalties on any money Bristol made using any of its Taxol patents, and Holton got a **five-year research collaboration deal** with Bristol chemists worth \$1.7 million.
- At the same time, FSU also got Bristol to agree to cover all costs associated with patenting anything Holton's lab came up with, including Taxol derivatives.

Licensing revenues generated

IP Statistics FY 1995 - 1999

ITEM	FY 95	FY 96	FY 97	FY 98	FY 99	Cumulative
Royalty [Taxol]	\$9,586,986	\$6,111,075	\$29,019,776	\$45,147,158	\$56,959,797	\$146.8M

IP Statistics FY 2000 - 2011

ITEM	FY 00	FY 01	FY 02	FY 03	FY 04	FY 05	FY 06	FY 07	FY 08	FY 09	FY 10	FY 11	Cumulative
Royalty [Taxol]	\$67,241,277	\$61,497,501	\$38,393,926	\$20,153,897	\$10,381,456	\$1,552,090	\$0.0	\$0.0	\$382,802	\$273,959	\$92,161	0	\$200M

- So far FSU has as many as 60 patents pending from spin-off research Holton and his team have conducted on Taxol.
- Along with an enhanced reputation, FSU's benefit from Holton's research has been, plain and simply, millions of dollars.
- Florida State has been placed third in the nation for earning research dollars from royalties.
- Meanwhile, Holton has become a multimillionaire professor. By agreement with FSU, Holton got about \$140 million and a control of a \$50 million lab account.

Thank You