



IP associated risks in outsourcing

Alex Weisman, Ph.D

PDA Israel

Technology Transfer and Working with CMO/CDMO

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*Alex Weisman
Calathea Pharma*

www.calathea-pharma.com

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Outsourcing associated challenges and risk:

- **Budget;**
- **Time Schedule;**
- **Regulation;**
- **IP (patents; information; technologies; market data etc.)**
- **Quality;**
- **Compliance (data integrity);
etc.**

What is patentable for NCE's (small molecules):

- **Molecule (Markush);**
- **Method of action/ indication;**
- **Method of administration;**
- **Route of Synthesis;**
- **Physical properties;**
- **Active metabolites;**
- **Derivates (prodrug/ deuterated);**
- etc.**

IP associated risks:

- Lack of confidentiality (NDA, CDA etc. aren't a guarantee !) ;
- Information theft (for commercial and other purposes);
- Use the information for capturing the customer;
- By-passing the customer - subcontractor turns into the competitor;

Example - Information theft:

- Customer's process for production of KSM was transferred to trustable vendor in India;
- Highly positioned employee left the company with “know-how” and joined another vendor, who later offered same KSM for lower price - claimed as his own development;
- The impurities / residual solvents profiles/ levels between two products were completely identical - **very successful transfer :-) !**

Example:

Lack of confidentiality and Information theft (for commercial and other purposes);

The information generated during the development (upon commercial agreement and CDA) was used for patent application “as belongs to the subcontractor”.

(54) Title: AN IMPROVED PROCESS FOR THE PREPARATION OF ██████████ AND INTERMEDIATES THEREOF

(57) Abstract: The present invention relates to an improved process for the preparation of ██████████ and pharmaceutically acceptable salts thereof. More specifically the invention pertains to the improved process for preparing intermediates for the preparation of ██████████

Example:

Capturing the customer/ owner;

- Subcontractor (China) (company with high level expertise in synthetic organic chemistry) was approached for the development of new, more robust and effective RoS for NCE in advanced stage of clinical trials.
- Excellent work was done, new process was developed within time frames and budget;
- **The subcontractor submitted patent application (WO) for the RoS developed (!) claiming the ownership for the invention.**
- The customer had to **drop the new RoS and to pay another subcontractor** for the development of an alternative one (and they were lucky - there was an alternative one!)

Example:

By-passing the customer - subcontractor converts into competitor;

- The subcontractor was requested just to repeat the synthetic procedure from 1904;
- **The subcontractor smelt the “market potential” of the product and decided to become a competitor;**
- **Developed the process (on its own) and submitted patent application with the expectations for big market (finally, the idea died :-)**

189. Ame Pictet und A. Rotschy: **Synthese des Nicotins.**
(Eingeg. am 14. März 1904; mitgeteilt in der Sitzung von Hrn. P. Jacobson.)

Die Versuche, die der Eine von uns in Gemeinschaft mit P. Crépieux schon vor längerer Zeit unternommen hatte, um das Nicotin synthetisch darzustellen, hatten bis jetzt zu keiner vollständigen Lösung der Aufgabe geführt. Einerseits blieben in der Reihe der bereits

(54) **PROCESS FOR PREPARING RACEMIC NICOTINE**

(75) Inventors: **Guanghai Tian**, Shanghai (CN); **Guan Wang**, Shanghai (CN); **Xiaoguang Kong**, Shanghai (CN); **Rongxia Zhang**, Shanghai (CN); **Weiming Chen**, Shanghai (CN); **Jingshan Shen**, Shanghai (CN)

(73) Assignees: **Topharman Shanghai Co., Ltd.**, Shanghai (CN); **Topharman Shandong Co., Ltd.**, Shandong (CN)

Proper selection and allocation of outsourcing company should include careful evaluation of all relevant issues, including **IP protection levels and systems at customer and subcontractor's sites.
Thank you !**