


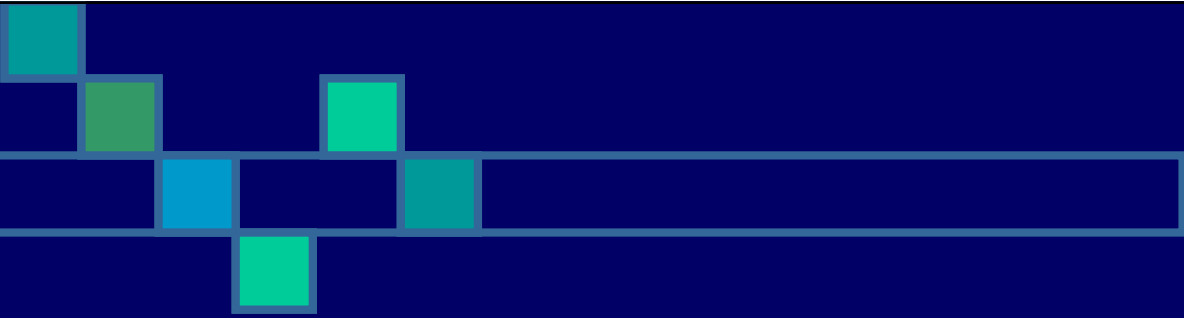


Orthopaedic Innovation: Bench, Bedside, Bank




Stephen P Makk, MD, MBA
A Seth Greenwald, D-Phil (Oxon)
Biomedical Engineering Committee
American Academy of Orthopaedic Surgeons

1

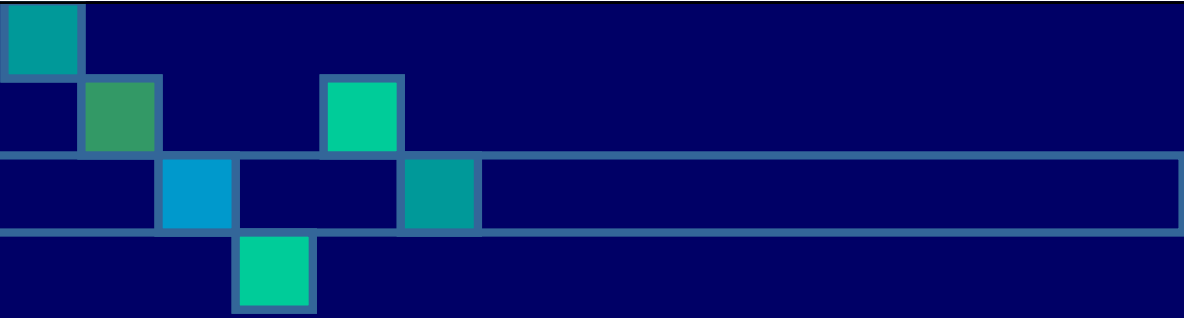


The Patent Process



www.uspto.gov

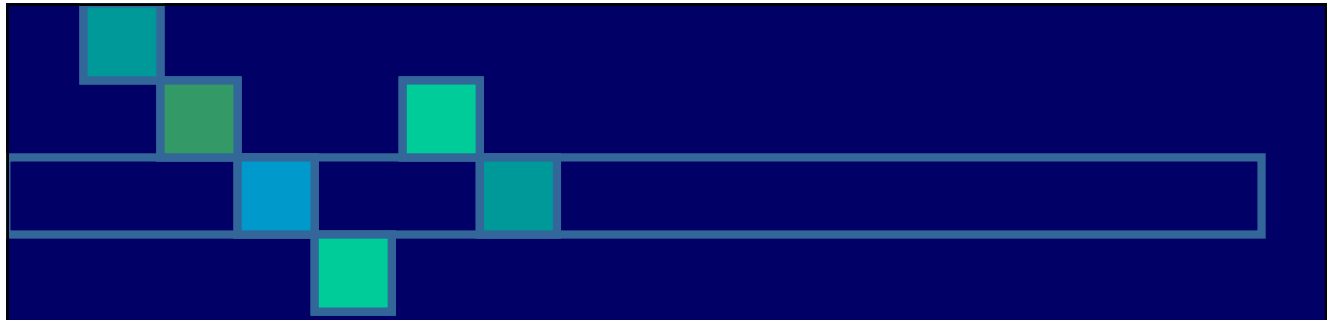
2



Patent:

A government grant allowing “the right to exclude others from making, using, offering for sale, or selling” the invention in the United States or “importing” the invention into the United States

3



Invent:

— ■ ■ ■ —

To produce or contrive something previously
unknown by the use of ingenuity or
imagination

-American Heritage Dictionary, Fourth Edition

4


Invention:

The reduction of an idea, device or technique
to practice

5



Patent Search




An exhaustive search of issued patents (“prior art”) to determine if the new application has been previously described

6



Prior Art:




All previously issued patents, literature,
publications and knowledge which bear on
the invention claimed in a patent application

Biotech Entrepreneur's Glossary

7



Patent Attorney:




A lawyer with special certification who represents inventors at proceeding at the Patent and Trademark Office. This is the only formally recognized legal subspecialty.

8



Patent Life:



Before June 8, 1995, patents typically had 17 years of patent life from the date the patent was issued. Patents granted after the June 8, 1995 date now have a 20-year patent life from the date of the first filing of the patent application.

www.fda.gov

9



Effective Patent Life:

Frequently less than 20 years because patents are often obtained before products are actually marketed. Factors influencing the length of the effective patent term include requirements in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act that certain products receive FDA approval before marketing. New human drug products generally must undergo extensive testing in animals and humans to show that the drugs are both safe and effective before FDA will approve the product for marketing.

www.fda.gov

10




The FDA Process



11



Food & Drug Administration (FDA):




The government agency of the US Department of Health & Human Services that regulates the safety and quality of medical devices, food, drugs, biologics, cosmetic, animal feed and drugs, radiation-emitting & combination products as mandated by the Pure Food & Drug Act of 1906 & the Pure Food, Drug & Cosmetics Act of 1938

12



New Drug Candidate:




A non-federally registered novel therapeutic chemical entity. This may be a slight yet significant chemical alteration of an existing compound.

13



Preclinical Study:



Animal studies that test and screen for safety, toxicity and efficacy as well as the evaluation of chemical characteristics and pharmacologic activity.

14



Investigational New Drug (IND):

A new molecule that has been screened for pharmacologic activity and acute toxicity potential in animals in preclinical studies, ready to be tested in its diagnostic or therapeutic potential in humans. At that point, the molecule changes in legal status under the Federal Food, Drug, and Cosmetic Act and becomes a new drug subject to specific requirements of the drug regulatory system.

www.fda.gov

15




Phase 1 Clinical Trial:

— ■ ■ ■ —
A drug study using generally 20-80 healthy human volunteers designed to determine the metabolic and pharmacological actions of the IND in humans, the side effects with escalating doses and early evidence of efficacy in humans.

16



Phase 2 Clinical Trial:



Controlled clinical study of generally several hundred human volunteer PATIENTS conducted to gather preliminary data on efficacy for a particular indication in patients with the disease of condition as well as risks and side effects

WWW.FDA.GOV

17



Phase 3 Clinical Trial:


Expanded controlled and uncontrolled trials on generally
100s-1000s of human PATIENTS intended to gather
additional safety and efficacy information and
risks/benefits that may be extrapolated to the general
population and used in physician labeling.

www.fda.gov

18



Clinical Hold:




The Center for Drug Evaluation & Research (CDER) may issue a clinical hold in a clinical trial if the study is UNSAFE or if the protocol is CLEARLY DEFICIENT in design.

19



New Drug Approval (NDA):



The vehicle through which drug sponsor
formally proposes that the FDA approve a
new pharmaceutical for **SALE & MARKETING**
in the United States

20

NDA Goals:

“ The goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions:

- Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
- Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain.
- Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.”

www.fda.gov

21

Phase 4 Trials:

Post-Marketing Trials

"A vital part of CDER's mission is to monitor the safety and effectiveness of drugs that are currently available to the American people. To meet this goal, FDA has in place postmarketing programs that monitor marketed human medical products for unexpected adverse events. These programs alert the Agency to potential threats to the public health. Agency experts then identify the need for preventive actions, such as changes in product labeling information and, rarely, re-evaluation of an approval decision."

22

www.fda.gov




The FDA Device Approval Process



23



Class 1 Medical Device




A medical device subject to GENERAL
CONTROLS by the FDA that poses a LOW
RISK profile to patients

24



Class 2 Medical Device




A medical device subject to both general and
special control or PERFORMANCE
STANDARDS

25



Class 3 Medical Device



A medical device that has insufficient assurance of safety & efficacy & lacks evidence to classify it as Class 1 or 2 device. It requires general controls & Premarket Approval Application (PMA).

26



Premarket Approval Application (PMA):

— ■ ■ ■ —

The FDA's process of scientific review to
ensure the safety and efficacy of Class 3
devices

www.fda.gov

27



510(k) Device

— ■ ■ ■ —
An FDA classification that allows a device to
go to market (market notification) because it
is found to be **SUBSTANTIALLY**
EQUIVALENT to existing Class 1 & 2 devices

www.fda.gov

28



Good Manufacturing Practices (GMP)



The FDA's Quality System (QS) similar to
1994 ISO9000 Standards that govern
manufacturing practices.

Entrepreneur

“Under-taker.” One who starts-up a business
or who undertakes business risk.

30

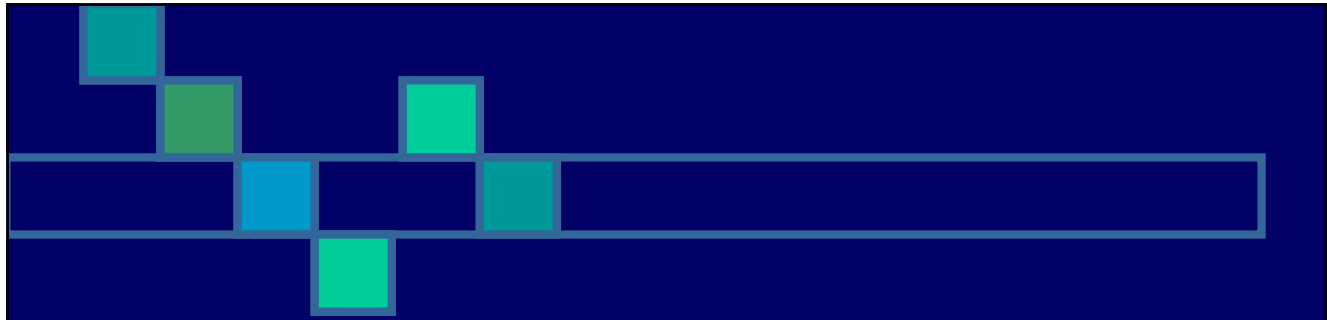


Bootstrapping




Employing personal resources- savings, earnings, credit cards, loans & sweat equity- to fund a start-up venture.

31



“Friends & Family”




Start-up capital borrowed from friends, family
and acquaintances, usually in return for
equity.

32



Small Business Innovation Research (SBIR)




SBIR is a highly competitive program that encourages small business to explore their technological potential and provides the incentive to profit from its commercialization. By including qualified small businesses in the nation's R&D arena, high-tech innovation is stimulated and the United States gains entrepreneurial spirit as it meets its specific research and development needs. Funded by federal departments.

www.sba.gov

33



Small Business Technology Transfer Program (STTR)




Nonprofit research laboratories are instrumental in developing high-tech innovations. But frequently, innovation is confined to the theoretical, not the practical. STTR combines the strengths of both entities by introducing entrepreneurial skills to high-tech research efforts. The technologies and products are transferred from the laboratory to the marketplace. The small business profits from the commercialization, which, in turn, stimulates the U.S. economy.

www.sba.gov

34



Seed Funding



A small amount of capital provided to entrepreneurs or inventors by individuals or funds to prove the feasibility of a concept or invention to qualify for subsequent start-up funding. Typically used to form a business plan, market research or for product development.

The Biotech Entrepreneur's Glossary

35



Angel Financing

— ■ ■ ■ —

A wealthy , private individual who funds a start-up seeking a greater return than from standard investments. In return for the investment, the angel receives a percentage of the company and it typically highly involved in business matters and governance.

The Biotech Entrepreneur's Glossary

36



Venture Capital

Formally managed private equity used to finance early to mid stage companies. This funding involves high risk investments but with the associated potential for high returns.

37



Initial Public Offering (IPO)

— ■ ■ ■ —

The initial issuance of stock sold in public markets. This is early stage graduation into the world of public (versus private) equity and is often the method by which early stage investors recoup their profits.

38