Managing IP for Access

Access to Medicines, Patent Information & Freedom to Operate
WHO-WIPO-WTO
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Freedom to Operate

- The “missing link”!
Freedom to Operate

- The “missing link”!

encouraging INNOVATION  enabling ACCESS
**Innovation: IP as a principal driver**

- An incentive: for risk taking
- A tool: to encourage investments in product development
- A mechanism: to make scientific advances widely available

**Access: IP as an instrumental driver**

- An incentive: for effective and useful partnerships
- A tool: to share valuable data, know how, etc.
- A mechanism: to make innovations faster available
What is Freedom To Operate?
What is Freedom To Operate?

From a legal perspective:

To have “assembled” all the IP rights for a specific product for a specific market and specific use.

What is Freedom To Operate?

From a business perspective:

A product development and risk management strategy.
What is Freedom To Operate?

Whether a patent is issued in a certain country is NOT a barrier *per se* to FTO.

How do I obtain FTO?

A. Legal and/or IP management strategies
1. License
2. Cross-license

3. Oppose 3rd Party Patent
4. Non-assertion Covenant

**Box 1: Nonassertion covenant from the software industry: Microsoft Open-specification Promise**

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Microsoft irrevocably promises not to assert any Microsoft Necessary Claims against you for making, using, selling, offering for sale, importing or distributing any implementation to the extent it conforms to a Covered Specification ("Covered Implementation"), subject to the following. This is a personal promise directly from Microsoft to you, and you acknowledge as a condition of benefiting from it that no Microsoft rights are received from suppliers, distributors, or otherwise in connection with this promise. If you file, maintain or voluntarily participate in a patent infringement lawsuit against a Microsoft implementation of such Covered Specification, then this personal promise does not apply with respect to any Covered Implementation of the same Covered Specification made or used by you. To clarify, "Microsoft Necessary Claims" are those claims of Microsoft-owned or Microsoft-controlled patents that are necessary to implement only the required portions of the Covered Specification that are described in detail and not merely referenced in such Specification. "Covered Specifications" are listed below.

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5. Seek compulsory license

World Trade Organization
How do I obtain FTO?

A. Legal and/or IP management strategies

B. R&D strategies
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B. R&D strategies

C. Business strategies

8. Wait and see (or dream on)
9. Merge or Acquire

10. Abandon project
In Practice:

A combination of several strategies implemented concurrently
Know-how

Regulatory dossiers

Data, designs, customer lists...

SOPs, lab manuals

Strains, plasmids, protein samples, antibodies...

Trade Secret
It's all about managing innovations for a better world...

...and for more fun and satisfaction in life.