



## Freedom to Operate (FTO) from a large company's perspective

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# Overview

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- ❑ What do we mean by FTO?
- ❑ What is the aim?
  - Why do we need FTO?
  - FTO vs. Granted patent
- ❑ When do we carry out FTO assessments?
  - Internal vs. External assessments
- ❑ Communicating the identified risks
- ❑ Can the risks be mitigated?

# What do we mean by FTO?

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The ability to *perform a particular commercial activity*

(e.g. commercialize a product, provide a service, perform a manufacturing process or use a product)

without “infringing” 3<sup>rd</sup> party’s valid IP rights.

# What is the aim?

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- Conduct a thorough assessment of the IP landscape to ... ..
  - ... identify all 3<sup>rd</sup> party IP rights
  - ... assess the level of the risk posed
  - ... consider how the risks can be managed
  - ... communicate conclusions to the business
  
- We respect valid 3<sup>rd</sup> parties IP rights

# Why do we need FTO?

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1. Patent rights are enforced through national courts
2. Interim injunction – prevent launch/withdraw infringing product prior to full trial.
3. Where the court concludes that the patent is infringed and valid it can order:
  - permanent injunction;
  - delivery up or destruction;
  - damages or account of profits; and
  - upon request, a declaration that the patent is valid and has been infringed.
4. Court proceedings are lengthy, can be technically challenging, expensive and outcome is hard to predict (there is always the appeal option!).
5. Identifying possible 3<sup>rd</sup> party IP rights posing risks as soon as possible is essential.

# FTO vs. Granted patent

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- A patent is a national right which merely gives the patentee the right to keep others from making, using or selling the invention in the particular country.
- Accordingly, other parties patent rights can present an FTO obstacle.
- Securing a patent after lengthy correspondence with an “awkward” examiner, although satisfying for the prosecuting attorney, does not provide an FTO.

# FTO assessment

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- Specialized patent searchers assess different databases using keywords and/or sequences.
- A consolidated report is issued, ideally, comprising granted patents and pending applications (patent rights) of some relevance, legal status etc.
- The report is analyzed in detail by a Patent Attorney for any risks posed by any patent rights.
- Validity/patentability assessments – require separate searches.
- A difficult and time consuming process.

# When do we carry out FTO assessments?

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- Internal projects –
  - ongoing basis and at all stages of a given project: before start, during the early research phase, identification of a candidate compound (small molecule or biologic) and during and during clinical development.
- External opportunities e.g. in-licensing or acquisition.



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# 1. Internal projects

# Internal FTO

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- An independent assessment of the patent status for a development candidate:
  - - to be carried out by a different attorney ideally a US attorney should be involved for any US-related issues
- Flush out all of the potential IP issues and have a sanity check on the state of the portfolio before the big investment:
  - review the patent strategy and identify any potential IP risks
  - Validity/patentability assessment
  - evaluate options to address risks
  - communicate conclusions appropriately and to the right management level

# Flow of information

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New attorney is provided with all details about the development candidate



FTO searches



Analyse searches and assess the risk (additional validity/patentability searches may be needed)



Communicate conclusions to team and management appropriately

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## 2. External projects

# FTO analysis

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- Conduct FTO searches to identify potentially relevant party rights relating to:
  - agent /compound
  - formulation/combination
  - process of manufacture (process steps and key intermediates)
  - Use
- Validity/patentability assessment
- If any issues arise:
  - Commercial impact?
  - Is the third party patent right valid/enforceable?
  - Is taking a license an option and consequences?

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- Communicating the risks

# Strategies for Obtaining FTO

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- Cross-licensing opportunity
- Design around to avoid infringement
- Wait for patent to expire
- Carry out activity in another, patent free, territory
- Argue non-infringement or potential invalidity
- Invalidate patent or render patent unenforceable in court  
i.e. “clear the way”

# Can the IP risks be mitigated?

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- Are any applications pending and can they be used to improve IP position?
  - consider filing 3<sup>rd</sup> party observations
- Is there a potential for future “*commercially relevant*” patent filings?
- Can any granted IP be improved?
  - post-grant amendments (e.g. India)
  - the new European limitation procedure
- Orange Book: de-listings, re-listings
- Can any 3<sup>rd</sup> party patents be opposed / challenged / licensed or acquired?
- Using an eventual deal structure:
  - minimal up-front payments and a greater emphasis on royalties;
  - option deal ... ..



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Thank you