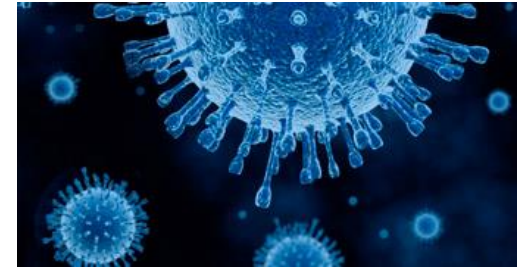
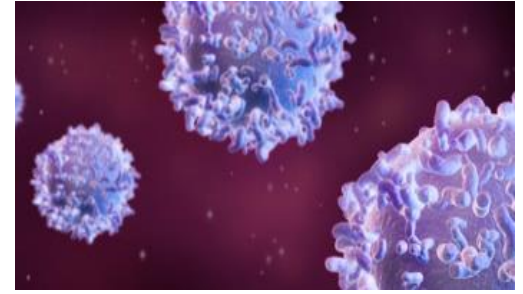


# PATENT PROCESS & CHALLENGES – WHEN IS THERE AN INVENTION?

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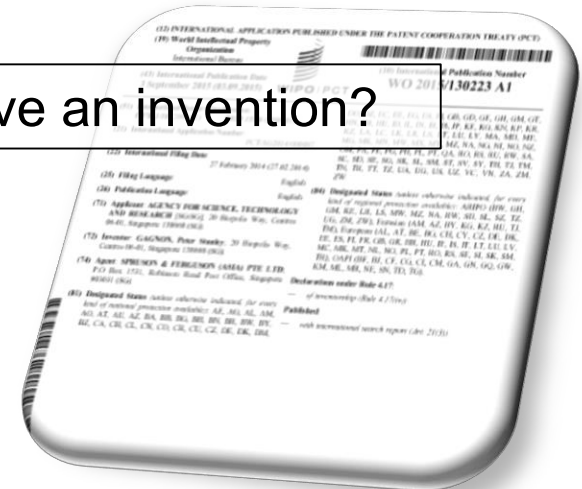
When do I submit a technology disclosure?



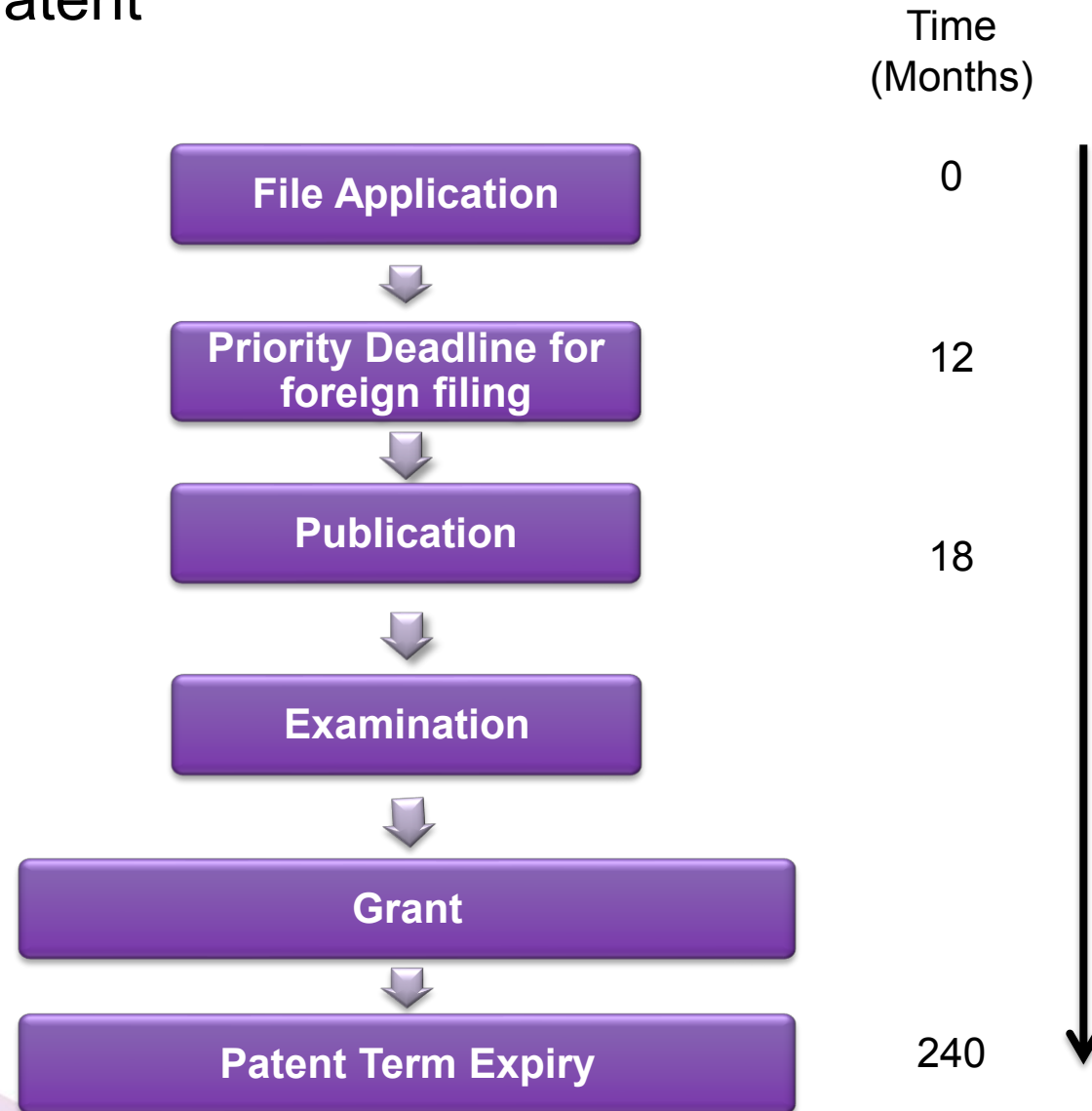
When you have identified an invention that is commercially attractive



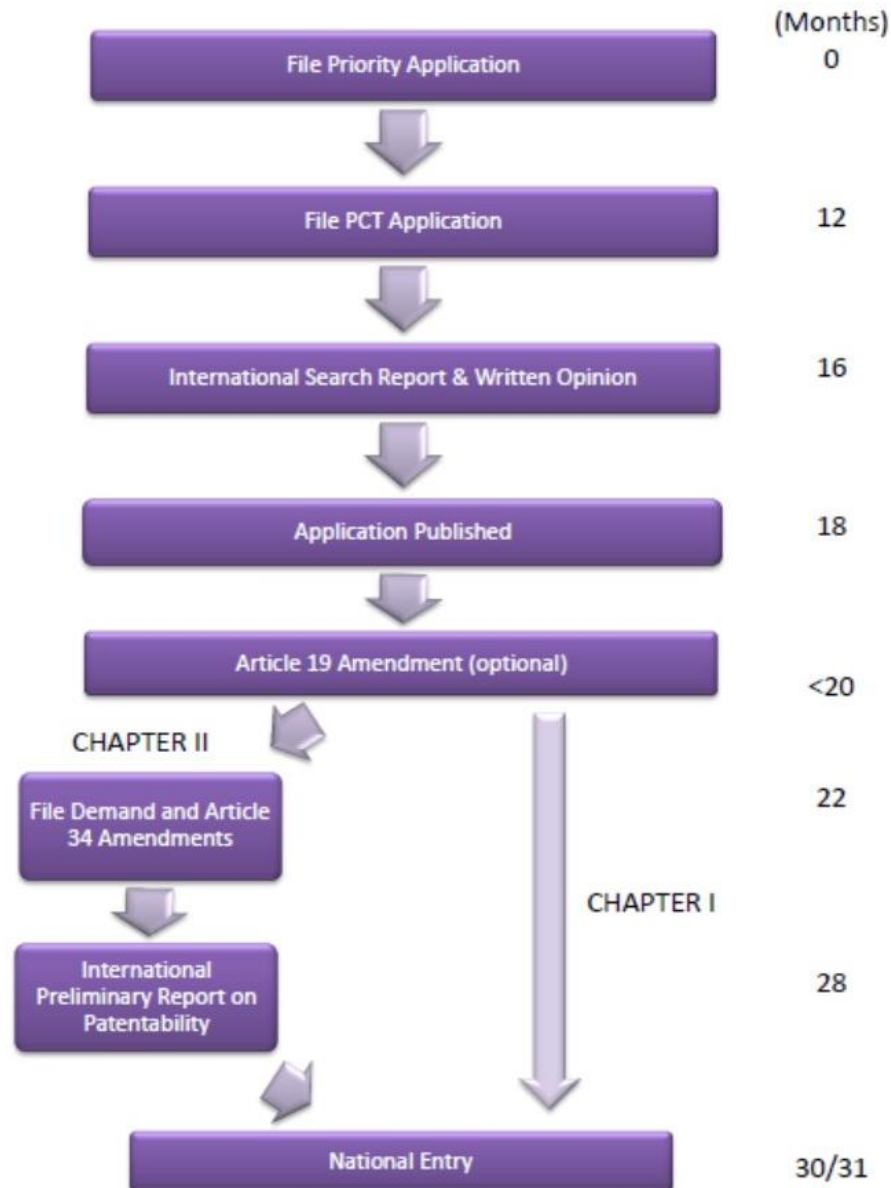
But when do you know you have an invention?

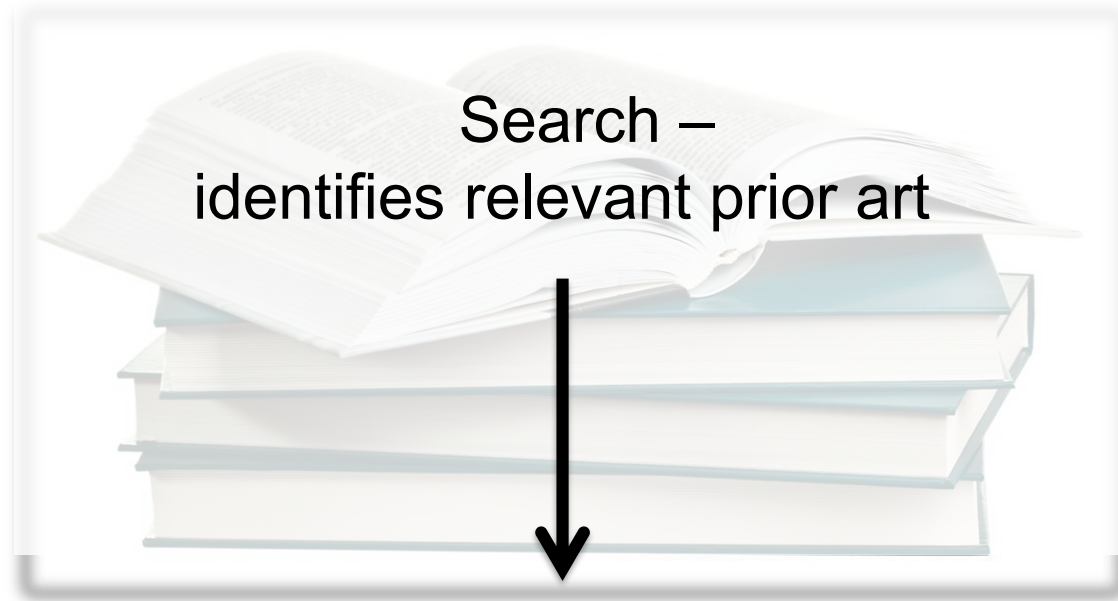


# Timeline of a Patent



# Timeline of a Patent





Search –  
identifies relevant prior art

Examination –

- ✓ novel
- ✓ inventive
- ✓ supported by the description
- ✓ utility

# A PATENTABLE INVENTION?

A patent will be granted in all fields of technology provided it is:

- **Novel -**

*An invention shall be taken as novel if it does not form state of the art (everything made available to the public before DOF), and will lack novelty if the specified combination of features has been anticipated in a prior disclosure.....*

## ■ Novelty

Subject matter has not been made available to the public

- A peer or non-peer reviewed journal
- A poster displayed at a scientific meeting
- An abstract submitted prior to a scientific meeting
- An lecture/seminar given at a scientific meeting
- Correspondence between collaborators e.g. email
- Personal or Institute websites
- PhD theses
- The exchange of materials between collaborators
- Prior Use

# A PATENTABLE INVENTION?

A patent will be granted in all fields of technology provided it is:

- Novel
- **Inventive**

*An invention comprises an inventive step if it is not obvious to a person skilled in the art who knows all matter in the state of the art*





## **Test Case:** Composition for treating migraine pain

- Two similar compounds X & Y
- Best administered in a thin film (known) that is applied to palate
- Simple applicator developed (modification of known product) for this purpose
- Data - Graph pain (migraine associated) v time showing one curve i.e. X is better than Y and a further graph showing X & Y better than either independently and cumulatively

## **Test Case: Composition for treating migraine pain**

### Claims

1. Compound X
2. Compound X for use as a medicament
3. Compound X for use in the treatment of migraine pain
4. The content of claims 1, 2 or 3 wherein compound X is supplemented with compound Y
5. Compound Y
6. Compound Y for use as a medicament
7. Compound Y for use in the treatment of migraine pain
8. The content of claims 5, 6 or 7 wherein compound Y is supplemented with compound X
9. A composition comprising X and Y
10. A combination composition comprising X and Y for use as a medicament
11. A combination composition comprising X and Y for use in the treatment of migraine pain

## Test Case: Composition for treating migraine pain

### **Search Results**

#### Cite 1

Derivative of compound X i.e. X-OH' is used to treat bad breath! (cosmetic / general health)

### **Claims**

1. Compound X
2. Compound X for use as a medicament
3. Compound X for use in the treatment of migraine pain
4. The content of claims 1, 2 or 3 wherein compound X is supplemented with compound Y

**Claims novel and inventive**

## Test Case: Composition for treating migraine pain

### Search Results

#### Cite 2

Precursor of compound X i.e. X-A' used topically to treat smelly feet!

Stated precursor is cleaved to produce X (*in vivo*) but product is X-A' (skin disease)

### Claims

1. Compound X
2. Compound X for use as a medicament
3. Compound X for use in the treatment of migraine pain
4. The content of claims 1, 2 or 3 wherein compound X is supplemented with compound Y

**Claims lack novelty except for particular use to treat migraine pain and combination of X & Y**

## Test Case: Composition for treating migraine pain

### **Search Results**

#### Cite 3

Compound X

X can be used to treat a list of diseases that is 3 pages long (including migraine pain)

### **Claims**

1. Compound X
2. Compound X for use as a medicament
3. Compound X for use in the treatment of migraine pain
4. The content of claims 1, 2 or 3 wherein compound X is supplemented with compound Y

**Claims lack novelty except for particular use to treat migraine pain and combination of X & Y**



## Test Case: Composition for treating migraine pain

**Cite 1.:** Claims novel and inventive (outside US)

**Cite 2.:** Claims lack novelty except for particular use to treat migraine and combination of X & Y

**Cite 3.:** Claims lack novelty except for particular use to treat migraine and combination of X & Y

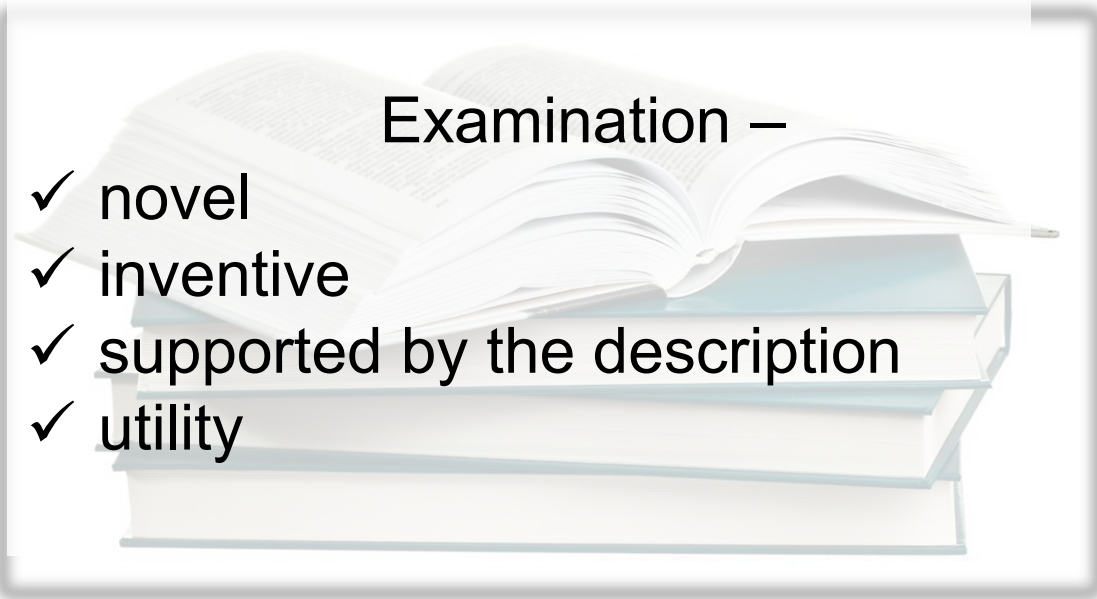
### Commercial impact?

**Cite 1:**  
Market Opportunity

**Cites 2 & 3:**  
May scupper opportunity if equivalent or derivative drug on market - due to tendency/scale off-label prescribing? Also FTO?

## Examination –

- ✓ novel
- ✓ inventive
- ✓ supported by the description
- ✓ utility



## Support – Data For Broad Claims

1. Claims define subject matter for which protection is sought – must be clear and concise and supported by the description
2. Basis in description for the subject matter of every claim and the scope of claims must not be broader than justified by extent of description and drawings, and also having regard to prior art

### Claim 1: Compound X

A method of producing compound X must be disclosed including essential details for production of same

Failure to disclose such a method could be used to demonstrate that the compound has not been produced – **claim not supported**



## Support – Data For Broad Claims

### Claim 2: Compound X for use as a medicament

- At least one use in the field of medicine
- No need for *in vivo* data but suitable *in vitro* data is required
- *Ideally:* cell models regarded by PSKA as representative of a particular disease

## Support – Data For Broad Claims

### Claim 3: Compound X for use in the treatment of migraine

- At least one use in the field of medicine
- No need for *in vivo* data but suitable *in vitro* data is required
- *Ideally:* cell models regarded by PSKA as representative of a particular disease

+ data that demonstrates alleviation of a symptom associated with the disease.  
(not necessarily human data required)

## **Support – Data For Broad Claims**

### **Claim 4:**

**The content of claims 1, 2 or 3 wherein compound X is supplemented with compound Y**

- a. A method for producing compound X with Y must be disclosed
- b. Use of the combination must be disclosed. But if both are known compounds and known to have such functionality, claim would be supported by knowledge of PSKA
- c. Use to treat migraine – same as above

## Support – Data For Broad Claims

Generalisations allowed varies in view of art – new field usually allows more generality

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### **General Rule:**

Not so broad that goes beyond invention yet not so narrow it deprives applicant of reward for disclosure of invention. Should be able to protect all obvious modifications

s  
e

A



## Support

- Claim regarded as supported unless there are well-founded reasons for believing that the skilled person would be unable to extend the particular teaching of the description to the whole of the field claimed by routine experimentation
- Support must be technical – vague statements provide no basis. Once raised as objection, onus on Applicant
- Not ground for opposition but can be raised against amendments filed during opposition
- Can also form pre-grant observations by 3<sup>rd</sup> parties



## Utility

Compound X for use in the treatment of migraine pains but example discloses that only when given at a dosage of greater than 100 $\mu$ g compound x has an effect

In absence of dose in the claim, it does not achieve the desired technical effect of treating migraine pains and thus is not industrially applicable

**Lack of utility is ground of  
opposition/revocation**

### **Check list: When do I submit a technology disclosure**

- ✓ Novelty
- ✓ Inventive Step
- ✓ Support – can make/use technology - basic consideration
- ✓ Industrial Applicability – disclosed invention can do what we say having regard to how we described and claimed it

Thank you!

Any questions?

