

Freedom to Operate Analysis

Presented for

"Only One Theme" : An Awareness Campaign on
Innovation Management (Venture Centre)

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Dec 2022

Overview

- *Intellectual Property and its Types*
- *IP/Patent Infringement*
- *Freedom to Operate Analysis:*
 - *Definition*
 - *Requirements*
 - *Purpose*
 - *Methodology*
 - *Search Specifics*
 - *Data Summarisation for FTO Analysis*
- *Case Studies*
- *Summary*

Background



Trespass is knowingly **entering/using another owners' property** or land **without permission**, which encroaches on the owners' privacy or property and may lead to a punishable offence.

What constitutes an infringement of IP/Patent?

How can an FTO analysis help in avoiding infringement or legal risks?

What is Intellectual Property?

- Intellectual property:
 - Refers to **creations** of the mind, such as **inventions**; **literary** and **artistic works**; **designs**; and symbols, names and images used in commerce.
 - Is a set of **intangible assets**
 - Legally **protected by law**
 - Owned by a person or company

Types of IP

- Patents
- Copyright
- Trademarks
- Industrial Designs
- Geographical Indications
- Trade Secrets

Intellectual Property infringement

- Intellectual Property infringement means manufacturing, using, selling, importing or copying a patented product or process without the patent/IP owner's permission.
- The owner of a patent can take legal action against you and claim damages if you infringe their patent/IP.

Freedom to Operate ANALYSIS: Definition

"Freedom to operate", abbreviated "FTO", is usually used to mean determining whether a **particular action**, such as testing or **commercializing a product**, can be **done without reading on/infringing valid intellectual property rights**/patent(s) of others.

Also known as:

- Freedom to Practice Analysis
- An IP due diligence
- Risk assessment study
- IP Clearance Analysis

FTO Analysis - Requirements

- Understand the **Purpose** of an FTO Analysis
- **When** to carry out an FTO Analysis
- Define Methodology
 - FTO Search, Databases
 - Analysis
 - Claim Mapping, Interpretation
 - Data Summarization and Opinion

FTO analysis -Purpose

- To identify any **possible risk** :
 - *prior to launch of a product*
 - *prior to licensing a patented technology*
- To avoid liability of potential legal risk of **granted and enforceable patents**
- As a roadmap to design around the patent and thereby avoid potential legal risks of violating IP/patent rights

FTO analysis –When

- Before the **launch of the product** *or*
- **Before licensing agreements** or other royalties are being negotiated between the subject patent holder and a 3rd party interested in practicing its claimed subject matter.
- Also generally sought at the **beginning of technology development/pilot scale plant development**, when the client is considering the benefits of the project

FTO Analysis - Methodology

- *FTO Search:*
- Develop the search strategy with the use of:
- Keywords,
- Patent classification codes (IPC/CPC)
- Include Citations,
- Subject Specific Requirements:
 - Chemical Structure Search –Exact, Substructure, Markush Structure
 - Designs, Devices –Figures
 - Gene sequences etc

FTO Search Specifics

- Need to describe the invention/product as completely as possible
- A partial description leads to a partial FTO search and analysis and potential error

FTO Search Specifics: Two types of information

- **Technical information**
- WHAT is the product
- Answer: Technical description of the product - technical field, components, steps, functions, features, limits, etc
- How does it help IP Analyst
 - To design the right search for this invention
 - Generate key words
 - Find patent classification codes
 - Build search strings

- **Business information**
- **WHERE** does the client plan to use the product?
- **WHEN** does client plan to use the product in each country?
 - Answer: Knowledge of countries and time frames to search; more technical details
- How does it help IP Analyst
 - Business information makes the search more accurate and efficient
 - Find the right patent databases
 - Choose languages and support tools
 - Decide what time limits could be applied

FTO Search and Analysis

- SEARCH for patent documents with claims that might cover the product
- ANALYZE **potentially relevant** patent documents to determine :
 - (1) Do any claims appear to cover the product?
 - (2) Is the **product and its features** found in an granted & enforceable patent?
 - (3)Is the patent free to use? Is it in the public domain?

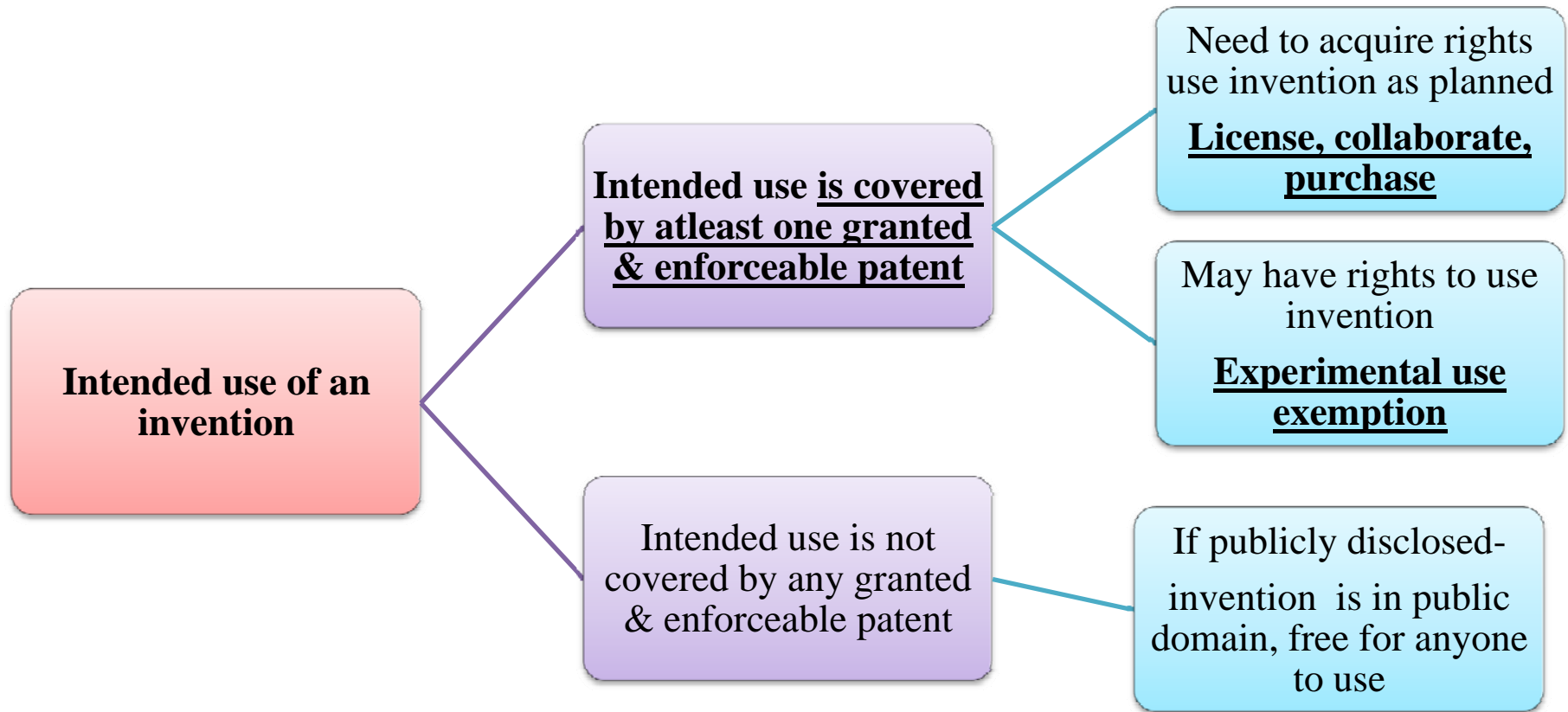
FTO Analysis

- Product feature/s analysis can comprise of:
 - Constructing a claim tree of the identified patent claim
 - Focus on independent claims
 - Followed by dependent claims
 - Subject Specific Analysis:
 - Chemical : Markush Claim analysis, enumeration
 - Substitution variation (R groups, atoms etc)
 - Homology variation (alkyl, alkoxy, aryl etc)
 - Biological: Sequences, Peptides, Amino Acids etc
 - Engineering: Devices, Apparatus, its arrangement etc
 - Finally **map/compare the features of the product to the claims of the patent**

FTO -Data Summarization

- Enlist the details of the identified & potentially relevant patents, assignee, dates(filing/grant) etc
- Enlist the **claims that read on the features of the product**
- Enlist the **geographic restrictions**, family details
- Enlist the **patent term expiration data, legal status** for the identified and relevant patents
- Present an opinion on whether a product, process or service may be considered to be of potential risk to the identified patent(s) owned by others.

Inventions, patents, public domain, rights to use



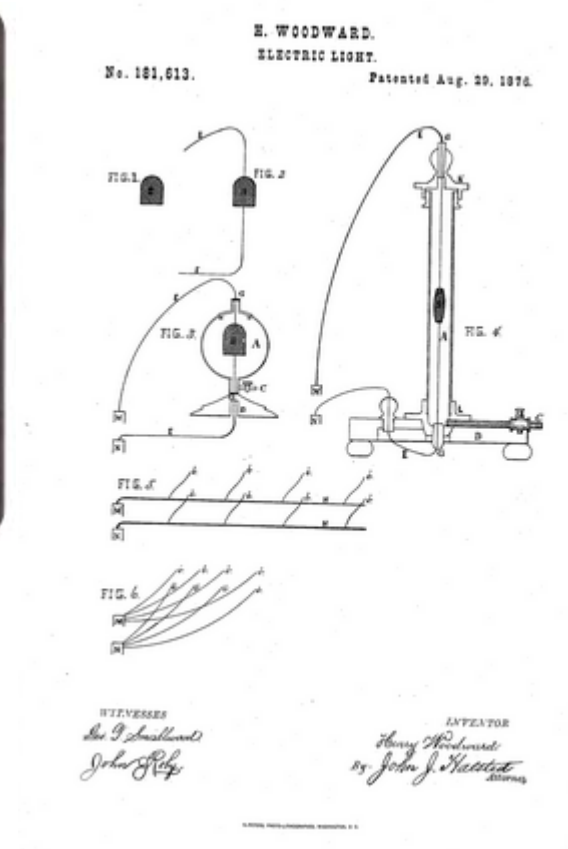
FTO- Case Study

Who Invented the Light Bulb??



Thomas Edison!

Henry Woodward Mathew Evans



Inventor: Henry Woodward
Mathew Evans

Patent No: CA3,738 & US patent

Grant date: 1874-08-03

Title of the Invention: Electric light

A **carbon** in combination with a **lamp** or **other suitable vessel** filled with **rarefied gas**, possessing the property of not chemically combining with the carbon

Exclusive License



Thomas Edison obtained an exclusive license to the Canadian patent.

Thomas Edison developed his own design of incandescent lamp with a high resistance **thin filament of carbon** in a **high vacuum contained in a sealed glass bulb** having a long service life to be commercially practical.

Thomson Edison –US 223,898 : **Electric lamp, 1880**

Lewis Latimer. - major contribution to the development of electric lighting by inventing a longer-lasting filament. But he did not invent the lightbulb

US Patent No. 252,386 - Latimer's process of manufacturing carbons -1881

SITAGLIPTIN PHOSPHATE (JANUVIA) TABLET EQ 25MG BASE – Type-2 Diabetes

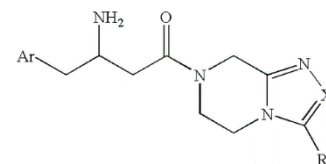


Patent/Expiry

Focus of the Invention

US7125873

-01/26/2023 –New
Chemical
Entity/Compound



US6699871-01/26/2023

Pharmaceutical
composition

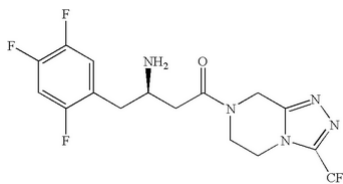
US7326708-05/24/2027

Salt form

CASE-2: SITAGLIPTIN PHOSPHATE (JANUVIA) TABLET EQ 25MG BASE –Type-2 Diabetes

Deconstruction of a Formulation Claim

1. A pharmaceutical composition comprising
(1) a first compound of the formula:



or a pharmaceutically acceptable salt thereof;

- (2) a second compound selected from the group consisting of:**

- (a) other dipeptidyl peptidase IV (DP-IV) inhibitors;
 - (b) insulin sensitizers selected from the group consisting of (i) PPAR γ agonists, other PPAR ligands, PPAR α/γ dual agonists, and PPAR α agonists, (ii) biguanides, and (iii) protein tyrosine phosphatase-1B (PTP-1B) inhibitors;
 - (c) insulin or insulin mimetics;
 - (d) sulfonylureas or other insulin secretagogues;
 - (e) α -glucosidase inhibitors;
 - (f) glucagon receptor agonists;
 - (g) GLP-1, GLP-1 mimetics, and GLP-1 receptor agonists;
 - (h) GIP, GIP mimetics, and GIP receptor agonists;
 - (i) PACAP, PACAP mimetics, and PACAP receptor 3 agonists;
 - (j) cholesterol lowering agents selected from the group consisting of (i) HMG-CoA reductase inhibitors, (ii) sequestrants, (iii) nicotinic alcohol, nicotinic acid or a salt thereof, (iv) PPAR α agonists, (v) PPAR α/γ dual agonists, (vi) inhibitors of cholesterol absorption, (vii) acyl CoA:cholesterol acyltransferase inhibitors, and (viii) anti-oxidants;
 - (k) PPAR δ agonists;
 - (l) antiobesity compounds;
 - (m) ileal bile acid transporter inhibitors; and
 - (n) anti-inflammatory agents; and
- (3) a pharmaceutically acceptable carrier.**

Also protected by a US patent 705XXXX

FTO-Requirement

- Assignee A wants to license the new anti-diabetic formulation to a client, who in turn wanted to manufacture and sell/export the product /anti-diabetic tablet
- Before entering into the licensing agreement the assignee will have to conduct the Freedom-to operate analysis for the formulation

Deconstruction of the product/claim under analysis

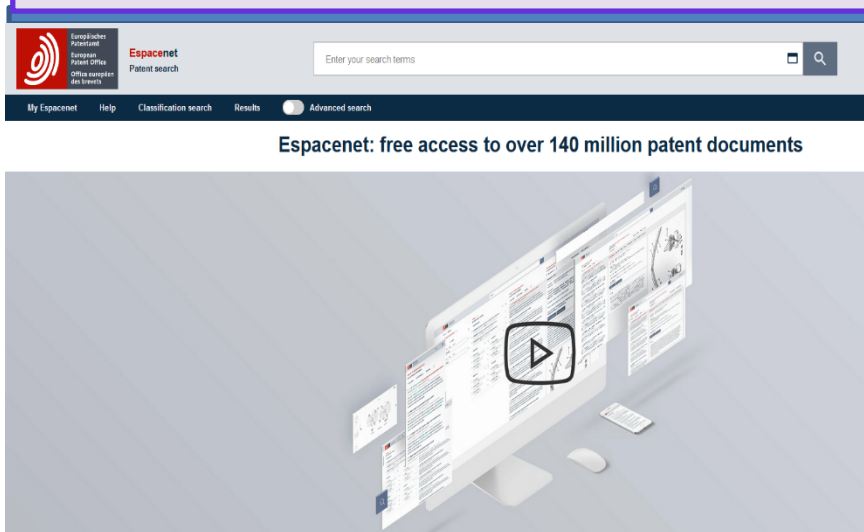
The US patent 705XXXX under consideration was deconstructed based on the focus of the claims and categorized as:

1. Proposed active compound
2. Pharmaceutical composition comprising of the bioactive
3. Process of making the formulation
4. Method of treatment

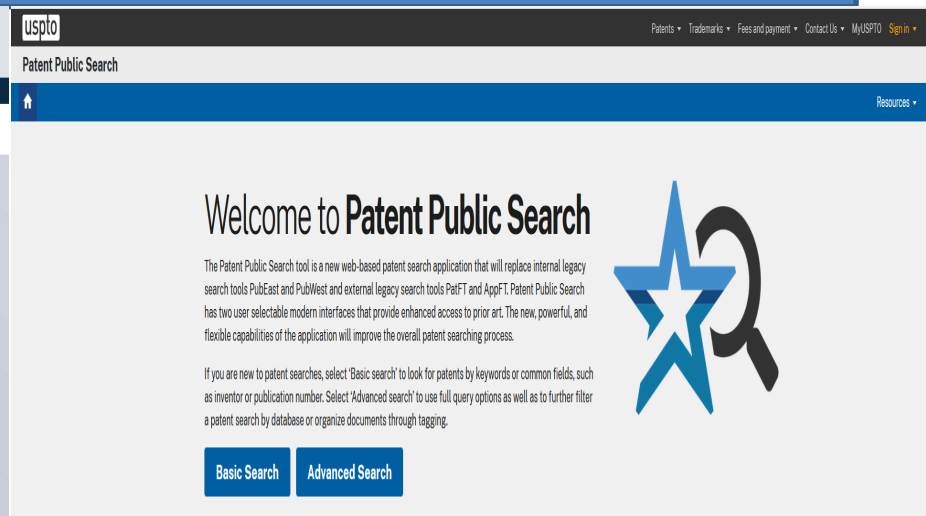
FTO Search

- Search focused on each of the element of the invention – i.e New Chemical Entity (NCE), Use of the active, formulation.
- Databases – Free as well as Subscribed databases
- Strategy – Subject Specificities, for example:
 - Chemical Inventions:
 - Active Pharmaceutical Ingredient (API) Structure Search, Patent Classifications, keywords, CAS Registry number, Chemical names etc
 - Formulation ingredients- excipients, solvents used, binder etc

Patent databases



The image shows the top section of the Espacenet website. It features the European Patent Office logo and the text "Espacenet Patent search". A search bar with the placeholder "Enter your search terms" is present. Below the search bar, there are navigation links: "My Espacenet", "Help", "Classification search", "Results", and "Advanced search". A prominent banner reads "Espacenet: free access to over 140 million patent documents". The background of the banner shows a 3D rendering of a computer monitor displaying patent search results, with a play button icon overlaid on the screen.

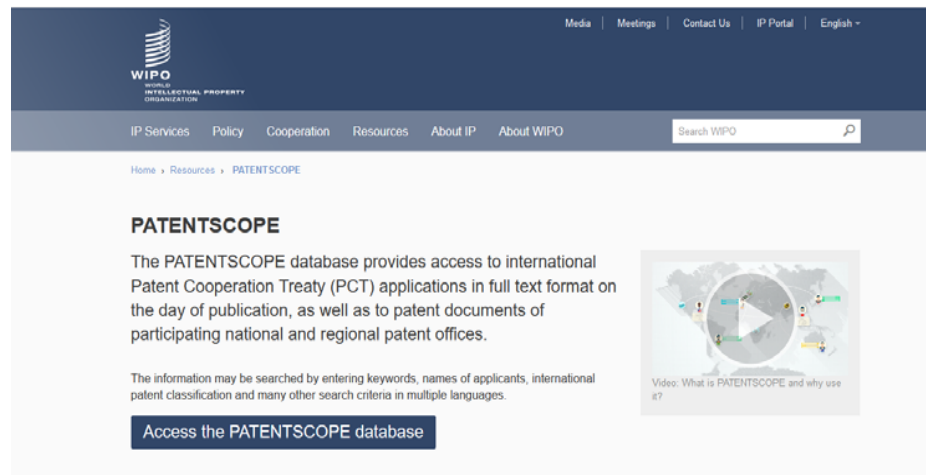


The image shows the top section of the USPTO Patent Public Search website. It features the USPTO logo and the text "Patent Public Search". A navigation bar includes links for "Patents", "Trademarks", "Fees and payment", "Contact Us", "MyUSPTO", and "Sign in". Below the navigation bar, a large blue banner reads "Welcome to Patent Public Search". To the right of the text is a large blue star logo with a magnifying glass. The main text describes the tool as a new web-based patent search application that will replace internal legacy search tools. It also provides instructions for new users, suggesting "Basic search" for keywords or common fields, and "Advanced search" for full query options. Two buttons, "Basic Search" and "Advanced Search", are located at the bottom of the main text area.



☐ Include non-patent literature (Google Scholar)

Search and read the full text of patents from around the world.



The image shows the top section of the WIPO PATENTSCOPE website. It features the WIPO logo and the text "WIPO PATENTSCOPE". A navigation bar includes links for "Media", "Meetings", "Contact Us", "IP Portal", and "English". Below the navigation bar, a search bar with the placeholder "Search WIPO" is present. The main text area is titled "PATENTSCOPE" and describes the database as providing access to international Patent Cooperation Treaty (PCT) applications in full text format on the day of publication, as well as to patent documents of participating national and regional patent offices. It also mentions that the information can be searched by entering keywords, names of applicants, international patent classification, and many other search criteria in multiple languages. A button labeled "Access the PATENTSCOPE database" is located at the bottom of the main text area. To the right of the text is a small graphic showing a globe with a play button icon and the text "Video: What is PATENTSCOPE and why use it?".

Patent databases

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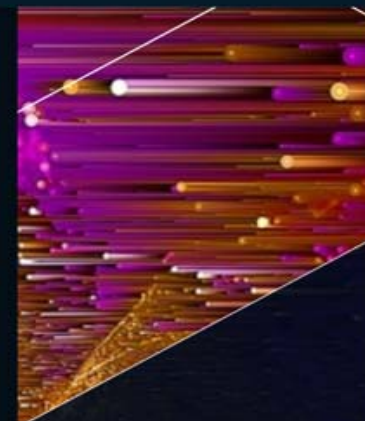
Workflow Integration

Advanced Analytics

CAS IP Services

CAS Registry Services

Knowledge Management



Analysis

- 10 patents of high interest were shortlisted and a claim to claim analysis was done:
- Amongst these one EP patent 229XXXX and US patent 669XXXXB2 was the most closest prior art reference.
- Is the active/API claimed by any product patent?
- Is the formulation claimed in any granted and enforceable patent?

SITAGLIPTIN PHOSPHATE (JANUVIA) TABLET EQ 25MG BASE –Type-2 Diabetes

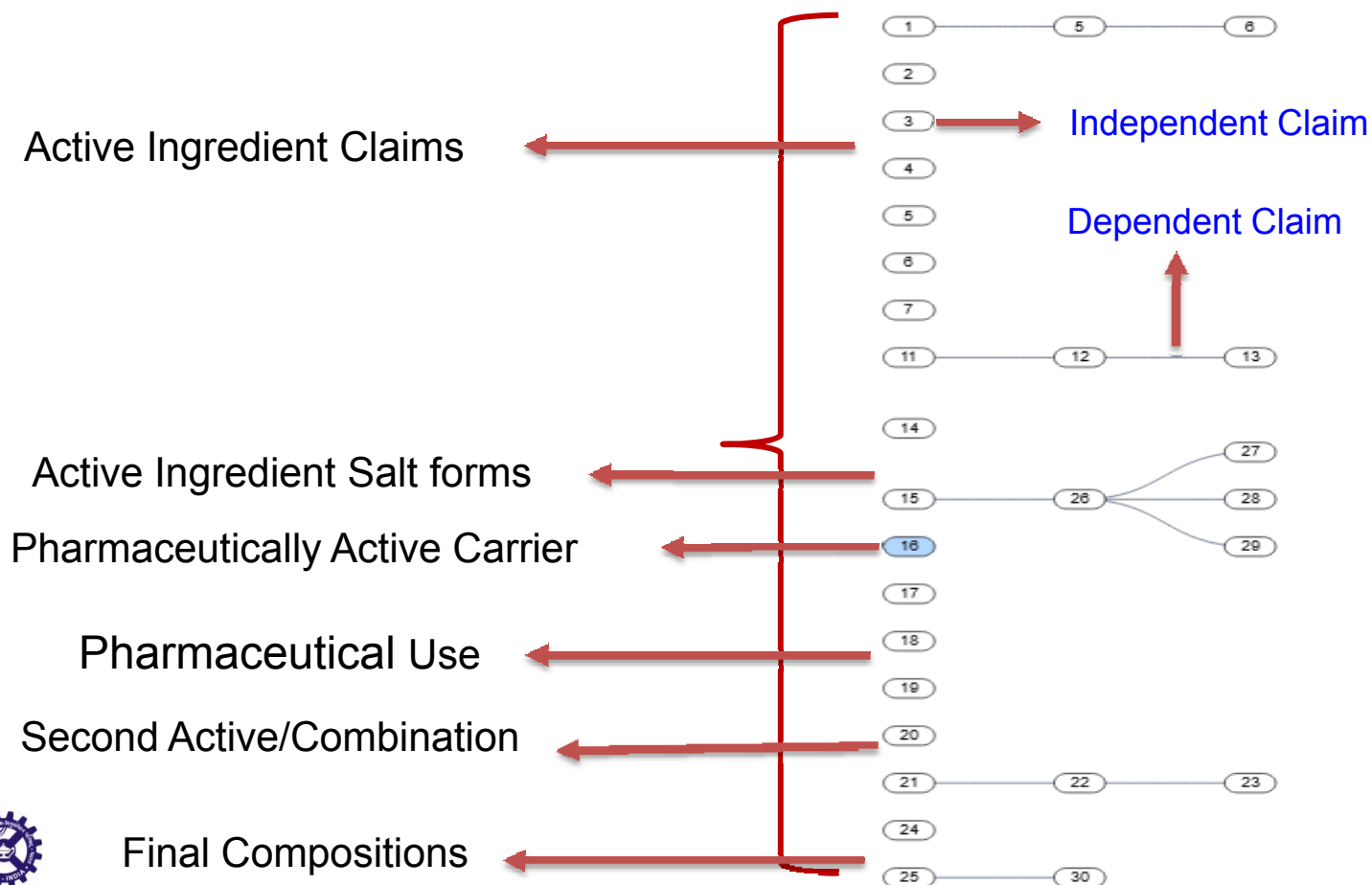
FTO Analysis/Mapping

Product Features	Feature 1 :Active ingredient of formula 1	Second therapeutic compound /Active	Pharmaceutically acceptable carrier	Application Diabetes	Possibilities
API					
Prior Art 1 US patent 669XXXXB2	Y Claim 1	N	N	Y Claim 5	Still in force-Take Licence or wait until the expiry
Prior Art : EP patent 229XXXX	Y Claim 1	Y Claim 20	Y Claim 15	Y Claim 6	Same as above

SITAGLIPTIN PHOSPHATE (JANUVIA) TABLET EQ 25MG BASE –Type-2 Diabetes

FTO Analysis/Claim Mapping: EP patent 229XXXX

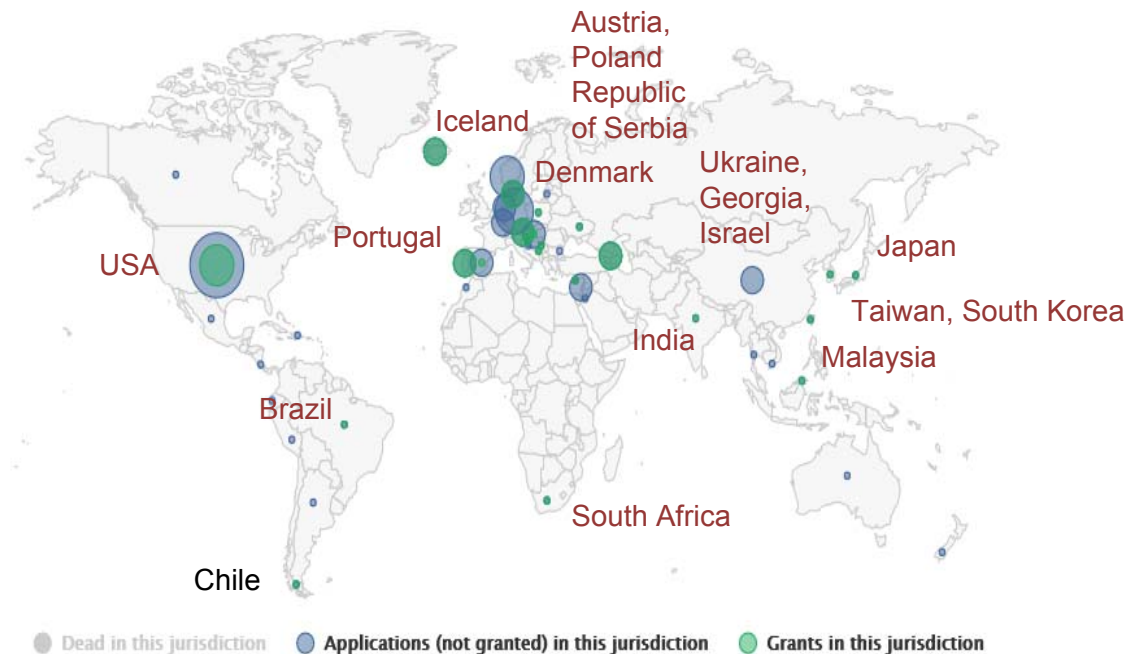
Prior Art : EP patent 229XXXX	Y :API	Y: Second Active	Y :Salt form	Y :Carrier	Y:Composition
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Data Summarization

- Listed the family members and the legal status of the patents claiming the scope of the invention- due to which the product if manufactured may face potential risk

Family map:



FTO Analysis :Insights

- The proposed formulation will have a restriction on the FTO option in the countries wherein the closest prior art (US) and EP patent is protected.
- As per the family member details the US patent was protected in 17, while in application stage in 15+ (needs to be monitored/tracked)
- Hence the client will not have a FTO option in these countries
- Options
 - Take a license from the company for using the API in the new formulation OR
 - Wait until patent term of the patent protecting the API is complete (i.e Patent expires/Open Domain)

SITAGLIPTIN PHOSPHATE (JANUVIA) TABLET EQ 25MG BASE –Type-2 Diabetes

FTO Analysis/Mapping

Product Features	Feature 1 :Active ingredient of formula 1	Second therapeutic compound /Active	Pharmaceutically acceptable carrier	Application Diabetes	Status Granted and Enforceable in
CASE -2					
Prior Art 1 US patent 669XXXXB 2	N	N	N	N	FTO -Yes

Summary

- Need to understand the invention: **technology and business plans**
- To develop the FTO search to **find potentially relevant documents**
- To **compare patent claims** with the **client's invention** during FTO analysis
- Use of technically specialized tools for generating inputs, cleaning up data, etc.
- Markush Claim/Structure analysis – important step for FTO analysis – chemical/pharmaceutical arts
- Identify **what is covered by patent rights**, and what might not be covered
- Discuss limitations, potential errors, and risks associated for further decision making.



Thankyou

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COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH

(MINISTRY OF SCIENCE AND TECHNOLOGY, GOVT. OF INDIA)

Updates