Freedom to Operate Analysis

Presented for

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

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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*

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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 paten/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

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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

FTO Search Specifics: Two types of information

- **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

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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.

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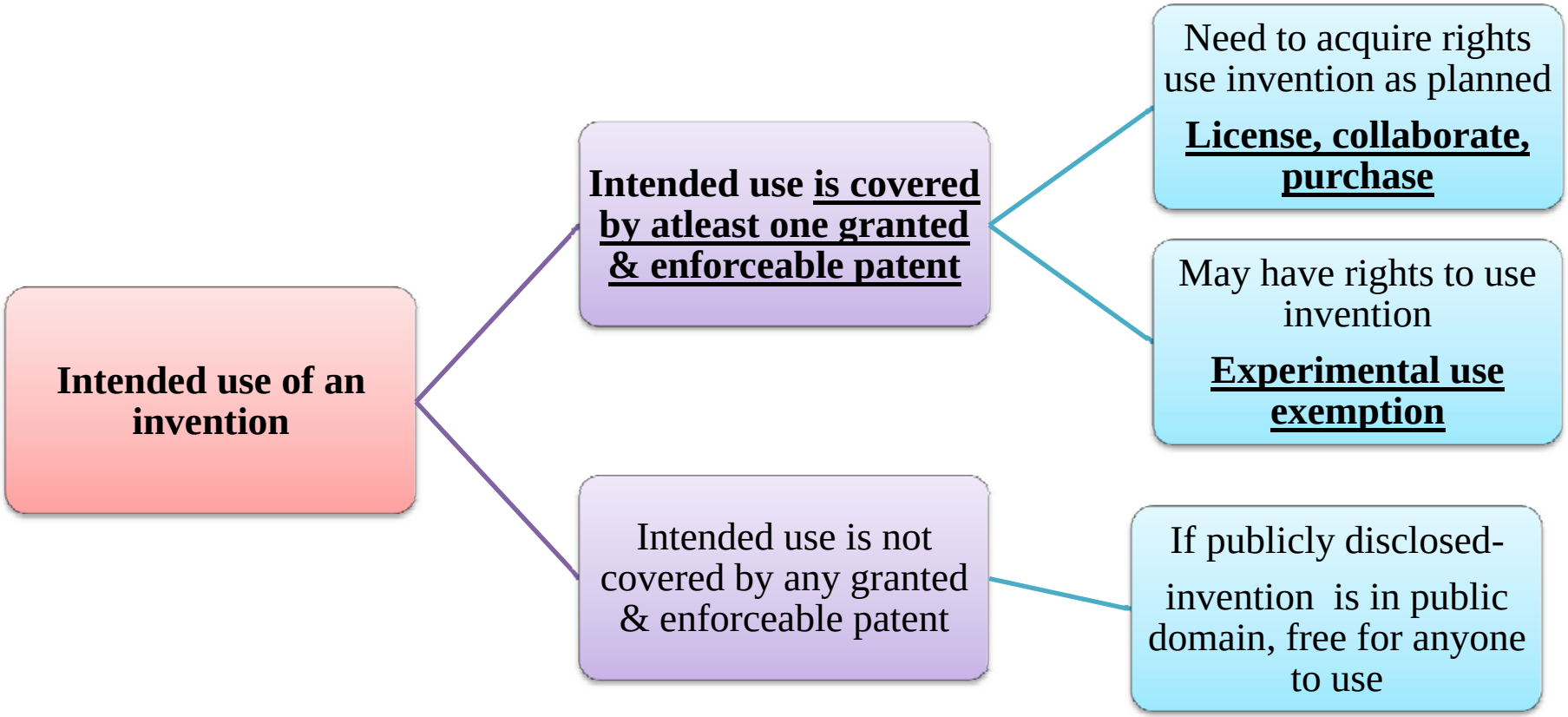
Inventions, patents, public domain, rights to use

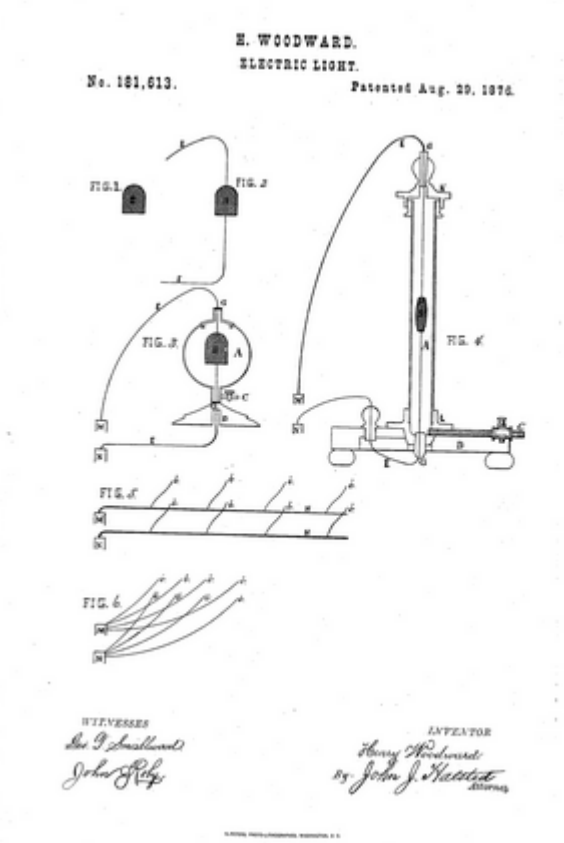


FTO- Case Study

Who Invented the Light Bulb??

Thomas Edison!

Henry Woodward Mathew Evans



Inventor: Henry Woodward Mathew Evans

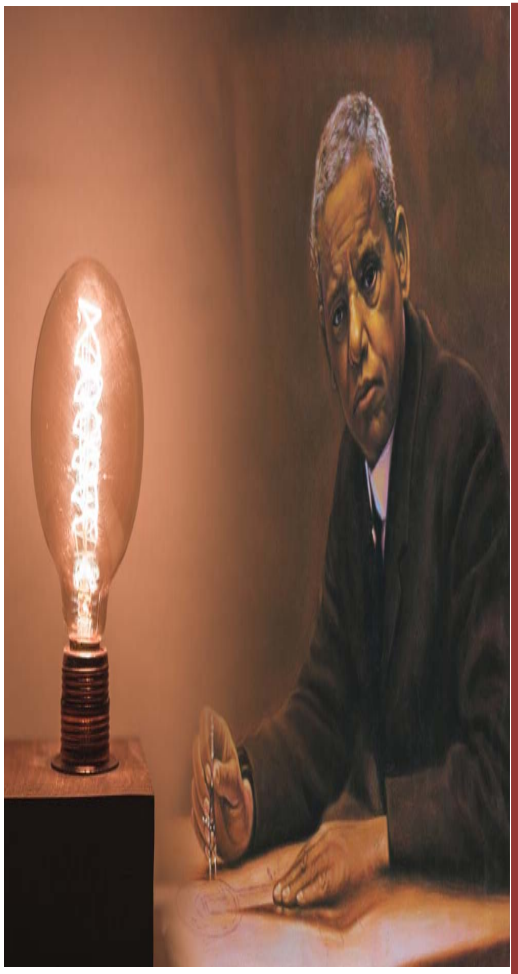
Patent No: CA3,738 & US patent

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.

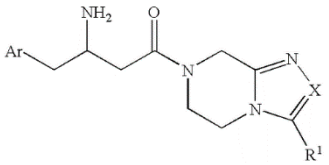
Thomas Edison developed his own design of incandescent lamp with a high resistance thin filament of carbon in a high vacuum contained in a sealed glass bulb having a long service life to be commercially practical.

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

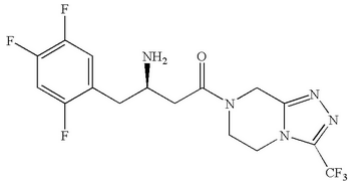
SITAGLIPTIN PHOSPHATE (JANUVIA) TABLET EQ 25MG BASE – Type-2 Diabetes

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) PPARγ agonists, other PPAR ligands, PPARα/γ dual agonists, and PPARα 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) nicotinyl alcohol, nicotinic acid or a salt thereof, (iv) PPARα agonists, (v) PPARα/γ dual agonists, (vi) inhibitors of cholesterol absorption, (vii) acyl CoA:cholesterol acyltransferase inhibitors, and (viii) anti-oxidants;
(k) PPARδ 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

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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

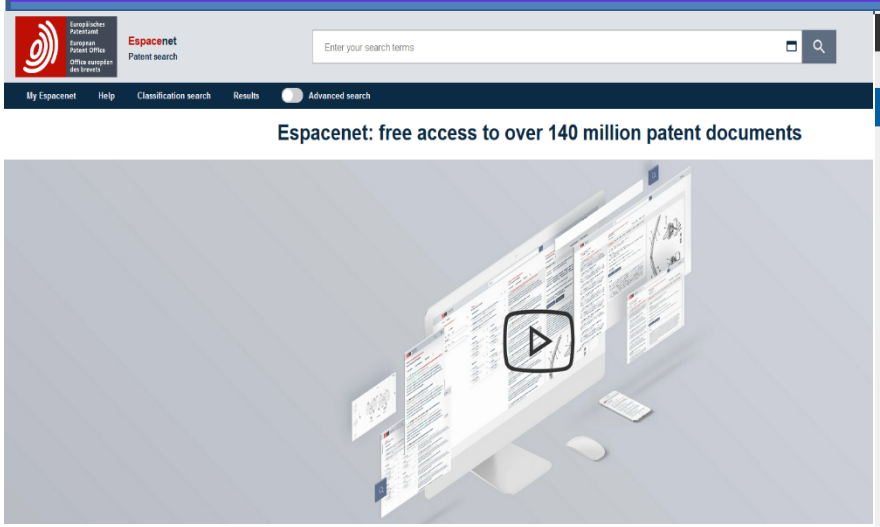
The US patent 705XXXX under consideration was deconstructed based on the focus of the claims and categorized as:

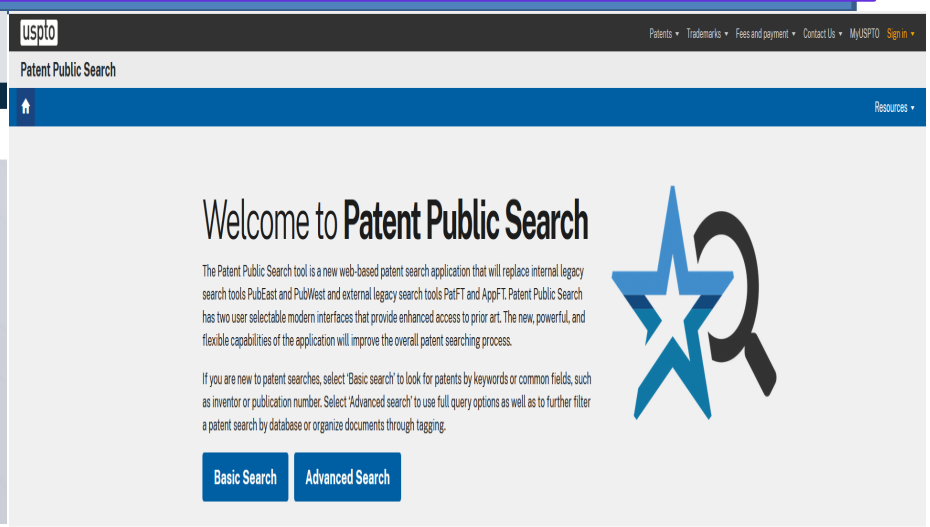
1. Proposed active compound
2. Pharmaceutical composition comprising of the bioactive
3. Process of making the formulation
4. Method of treatment

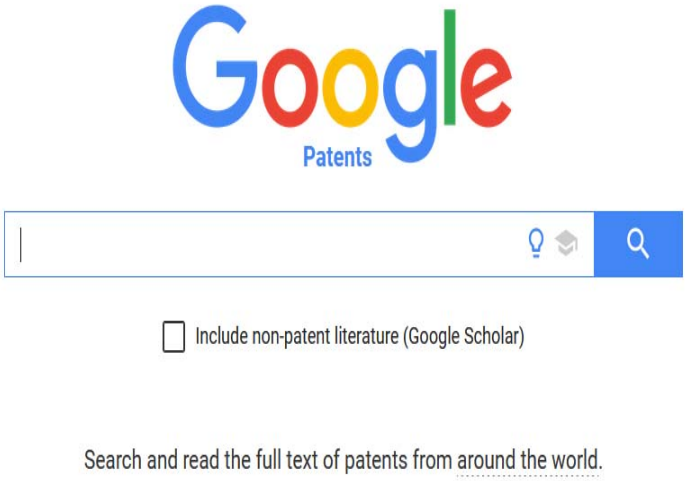
FTO Search

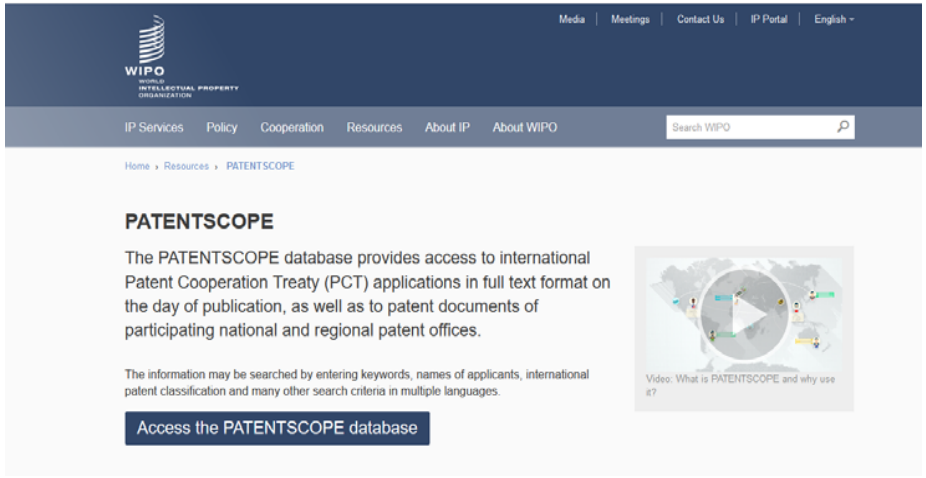
- Search focused on each of the element of the invention – i.e New Chemical Entity (NCE), Use of the active, formulation.
- Databases – Free as well as Subscribed databases
- Strategy – Subject Specificities, for example:
  - Chemical Inventions:
  - Active Pharmaceutical Ingredient (API) Structure Search,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

Patent databases

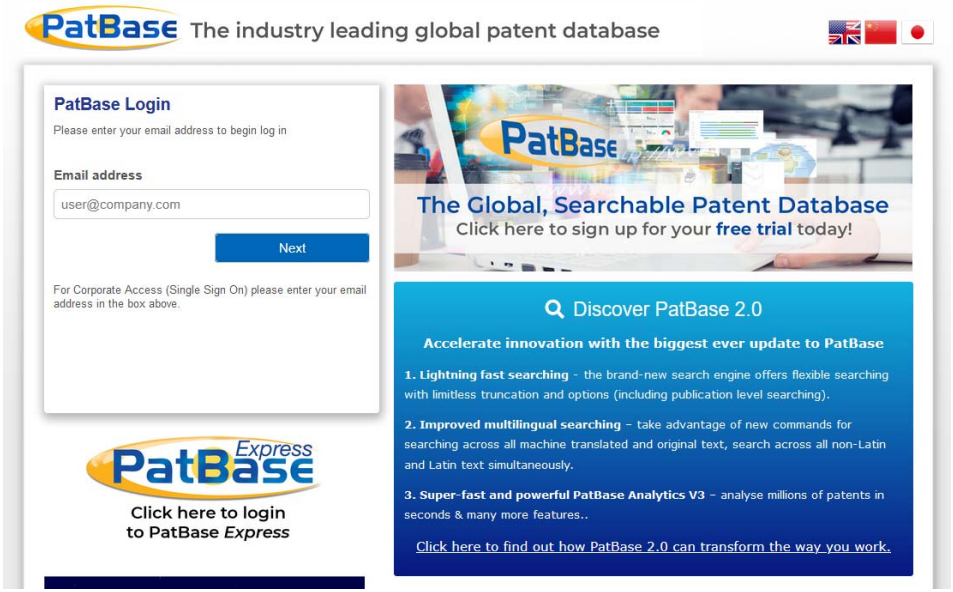


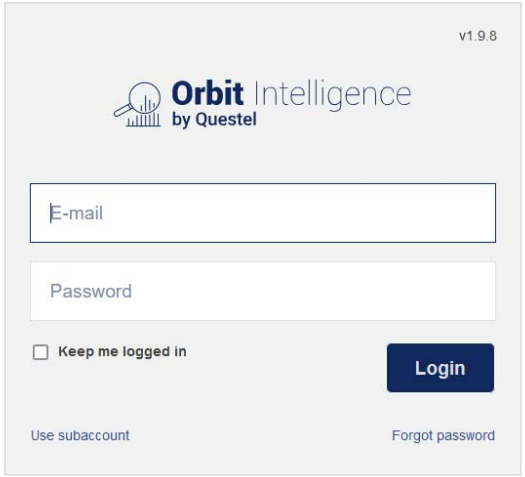


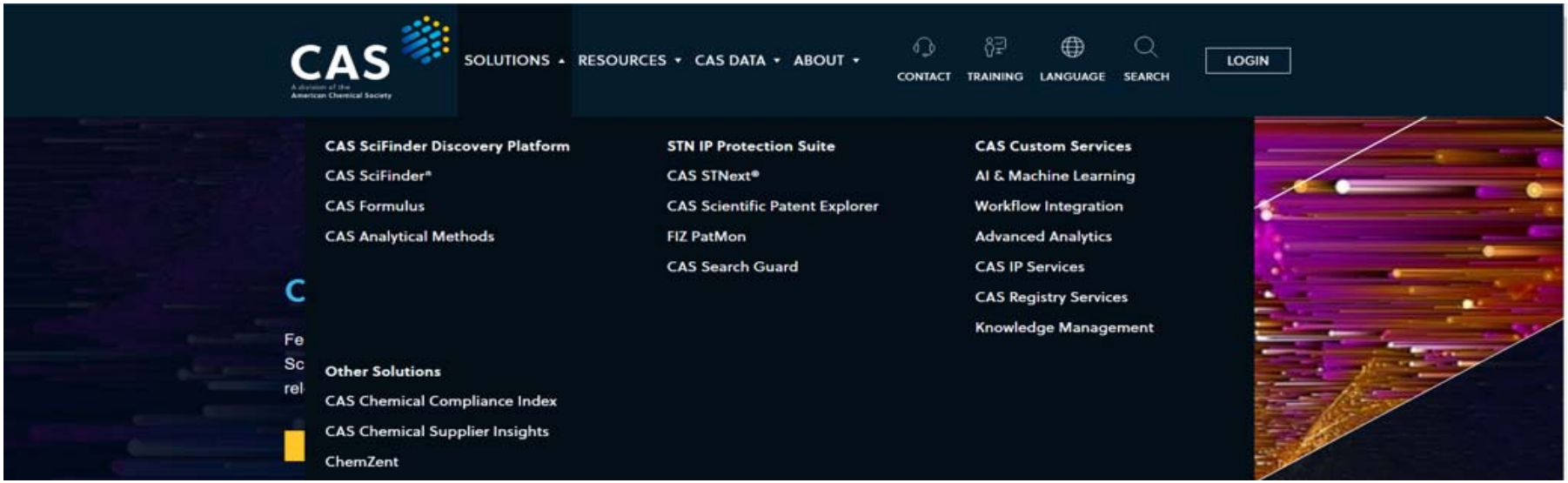




Patent databases







Analysis

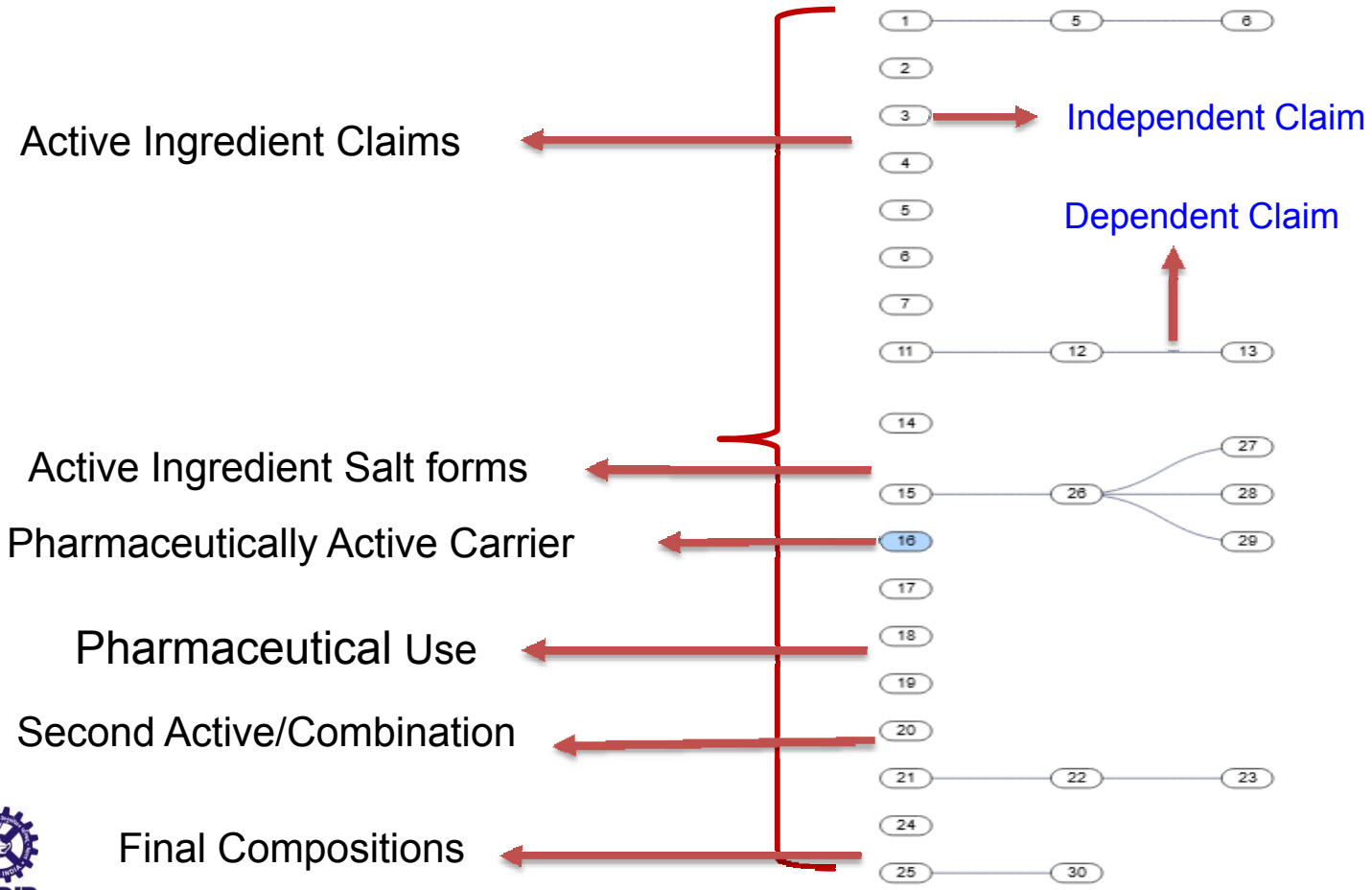
- 10 patents of high interest were shortlisted and a claim to claim analysis was done:
- Amongst these one EP patent 229XXXX and US patent 669XXXXB2 was the most closest prior art reference.
- Is the active/API claimed by any product patent?
- Is the formulation claimed in any granted and enforceable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

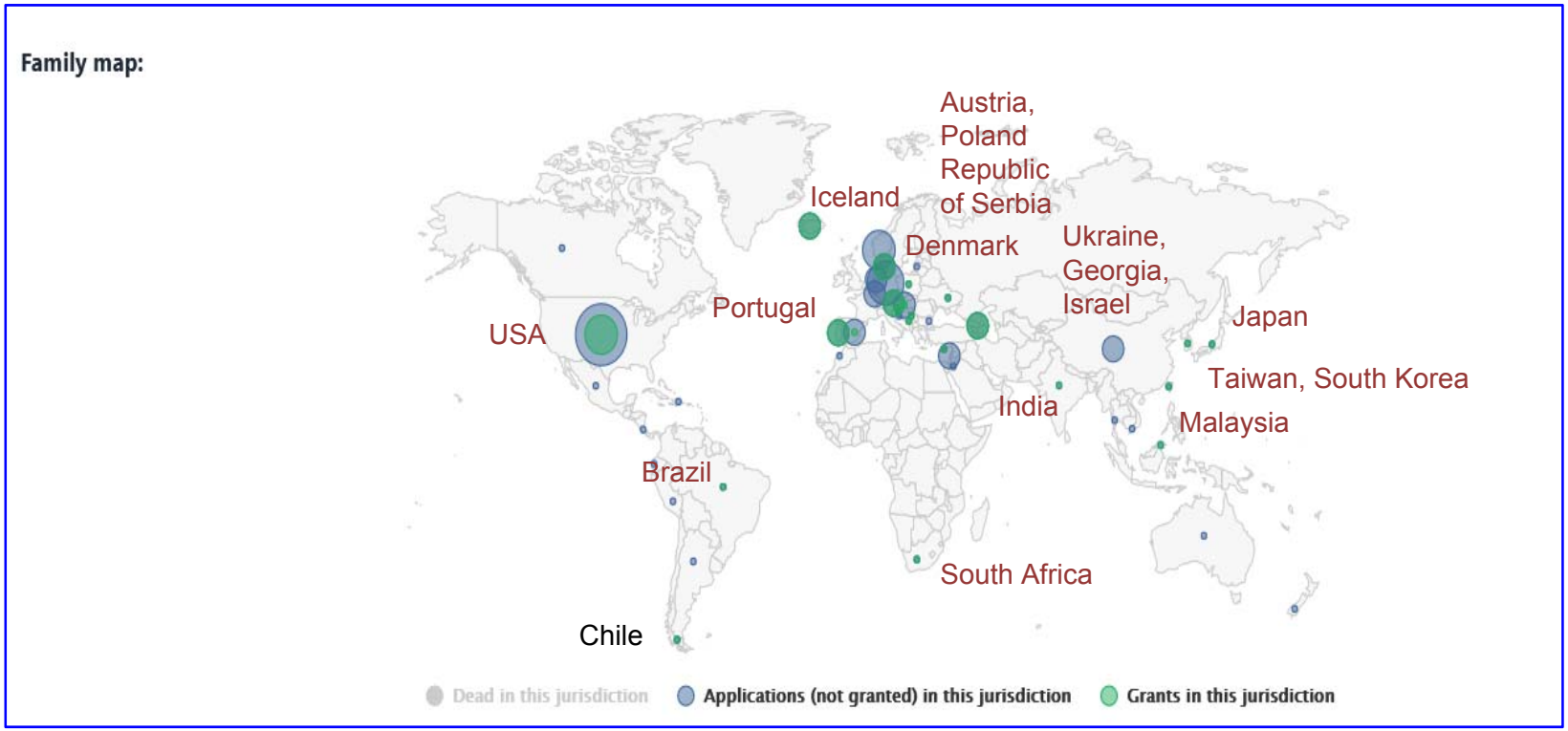
SITAGLIPTIN PHOSPHATE (JANUVIA) TABLET EQ 25MG BASE –Type-2 Diabetes
FTO Analysis/Claim Mapping: EP patent 229XXXX

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



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



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)

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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 669XXXXB2	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.

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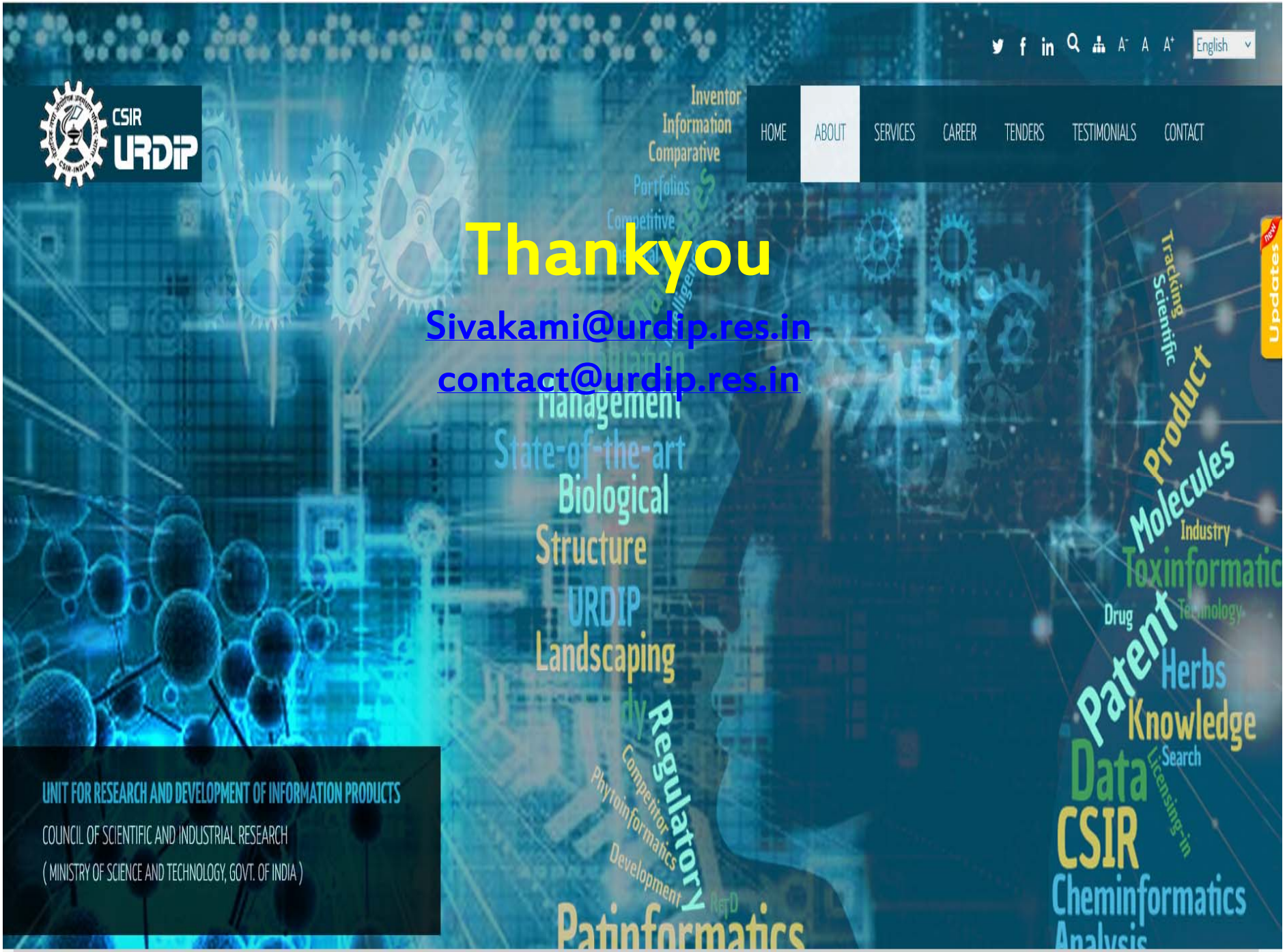
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