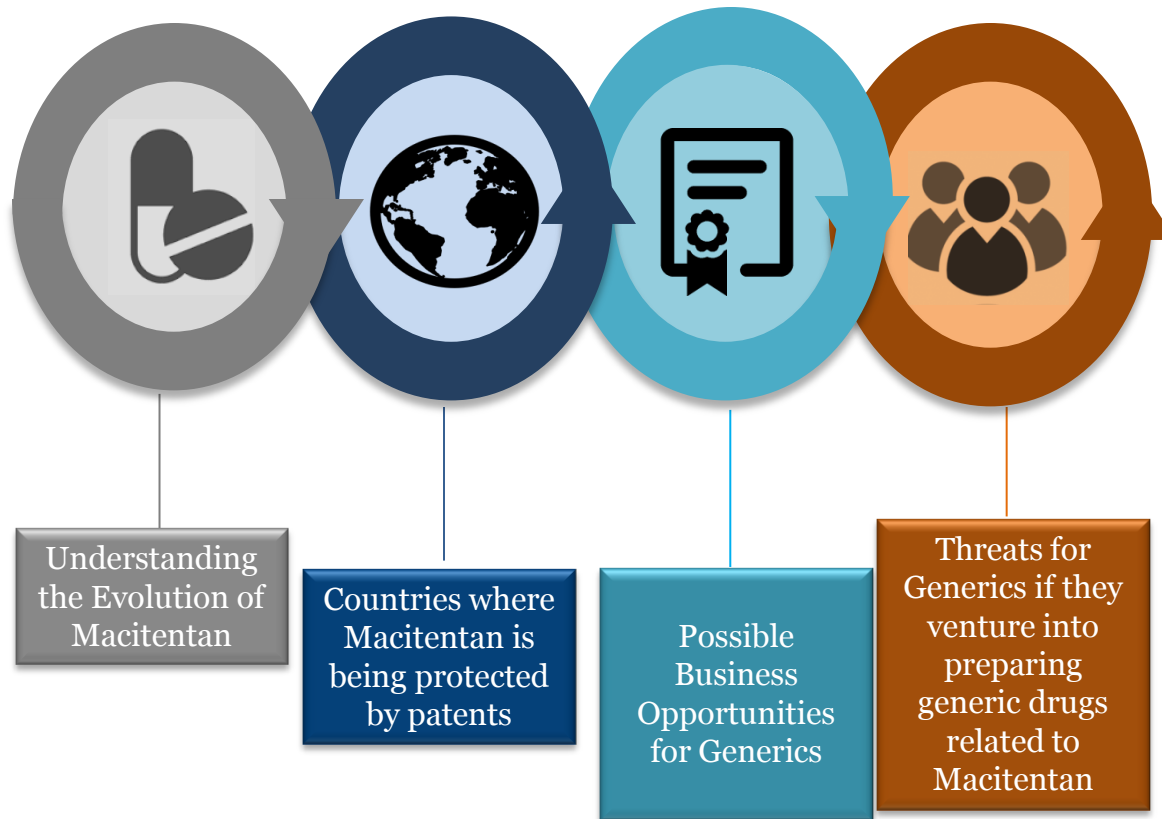


Things you should know about patents covering Macitentan (Trade name: Opsumit)

GreyB is an expert patent analytics organization with experience of conducting analysis for targeted research and assessment.

➤ *Topics of study*

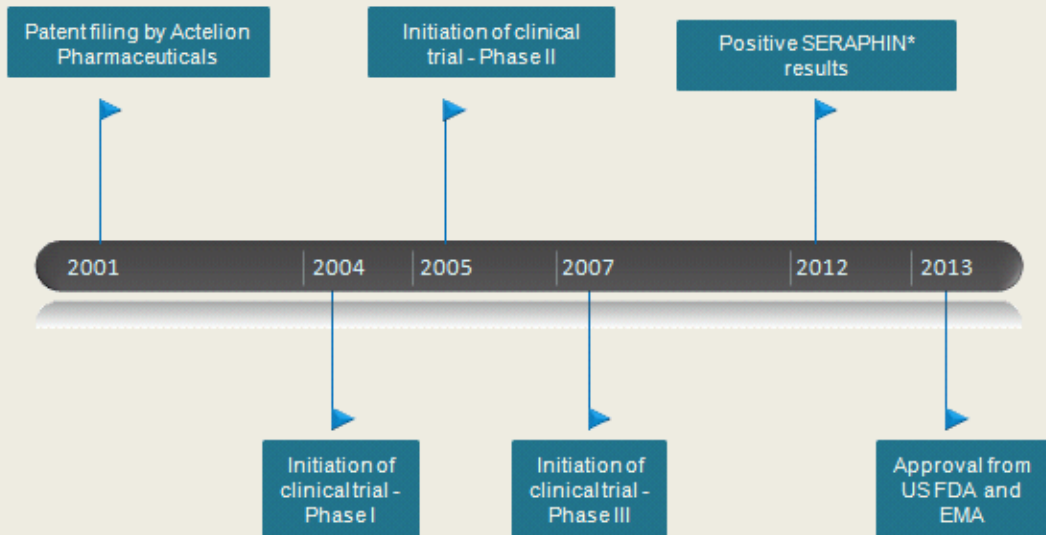


What is Macitentan and its exclusivities?



Description of Macitentan 1/2

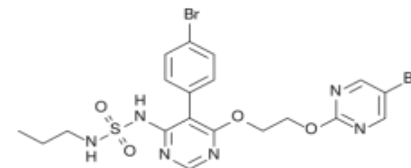
Timeline of Macitentan



21

- Twenty one unique patent families are published based on Macitentan.
- Out of these twenty one unique patent families, only one is the API (active pharmaceutical ingredient) patent i.e. it claims the only the structure of Macitentan.

Factsheet of Macitentan



IUPAC name

N-[5-(4-Bromophenyl)-6-[2-[(5-bromo-2-pyrimidinyl)oxy]ethoxy]-4-pyrimidinyl]-*N'*-propylsulfamide

Trade name

Opsumit, ACT-064992, Actelion-1, Opsumit, Zependo

Pregnancy category

US: X (Contraindicated)

Indication

Pulmonary Arterial Hypertension (PAH)

Routes of administration

Oral

Type of Drug

Orphan

Description of Macitentan 2/2



Macitentan is designated as Orphan Drug.

- Orphan drug are the drugs which are used for rare diseases.
- Market Exclusivity for Orphan designated drugs (ODE) :
US - 7 years



Macitentan is also designated as New Chemical Entity.

- New Chemical Entity, a drug that contains no active moiety that has been approved by the FDA in any other application.
- Market exclusivity for New chemical entity designated drug:
US – 5 years

Sales of Macitentan reaches \$99.75 Million (2015)



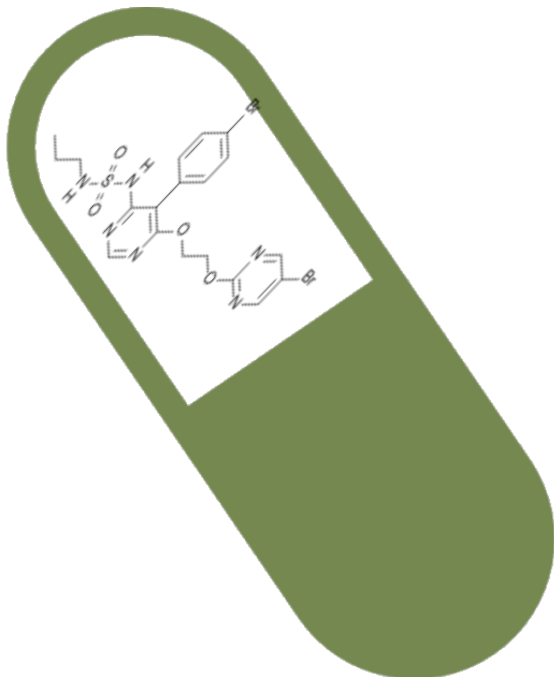
- OPSUMIT (Macitentan) was approved for treatment of PAH in 35 countries including United States in October 2013, the European union in December 2013 and Japan in March 2015 ([Source](#)).
- OPSUMIT sales have shown positive trends in most of Europe and North America.
- Other countries with increased sales include Australia, Kuwait and Israel ([Source](#)).



Which is the key patent of Macitentan and which are the countries in which it is being protected?



Key patent for Macitentan



US7094781

This patent claims the chemical structure of Macitentan. Other limitations are not present in it. Hence, it has high infringement potential – so, there are high stakes to generate any generic version of Macitentan.



Title

Sulfamides And Their Use As Endothelin Receptor Antagonists



Patentee

Actelion Pharmaceuticals Ltd.



International Nonproprietary Name (INN)

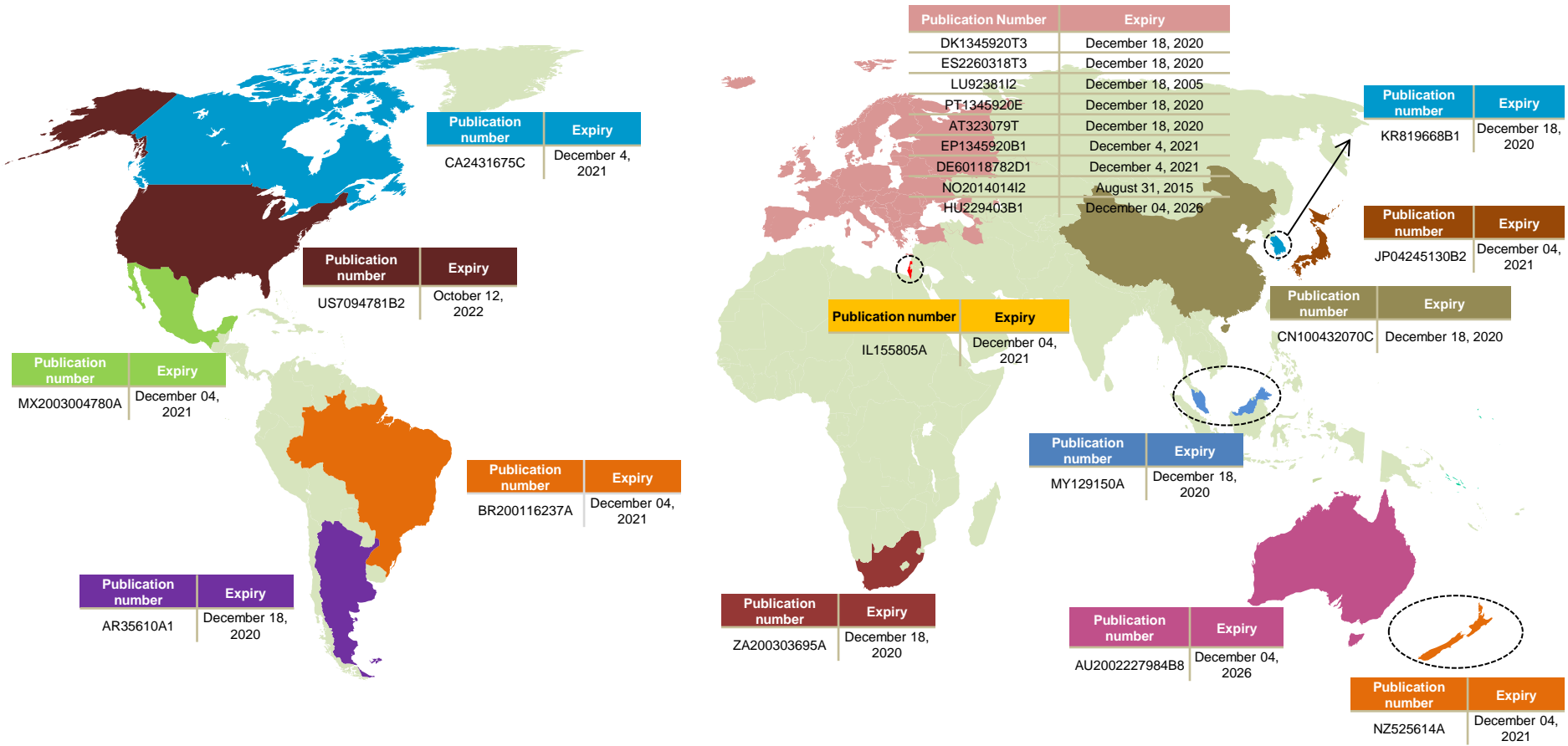
Macitentan



Market Coverage Across the globe

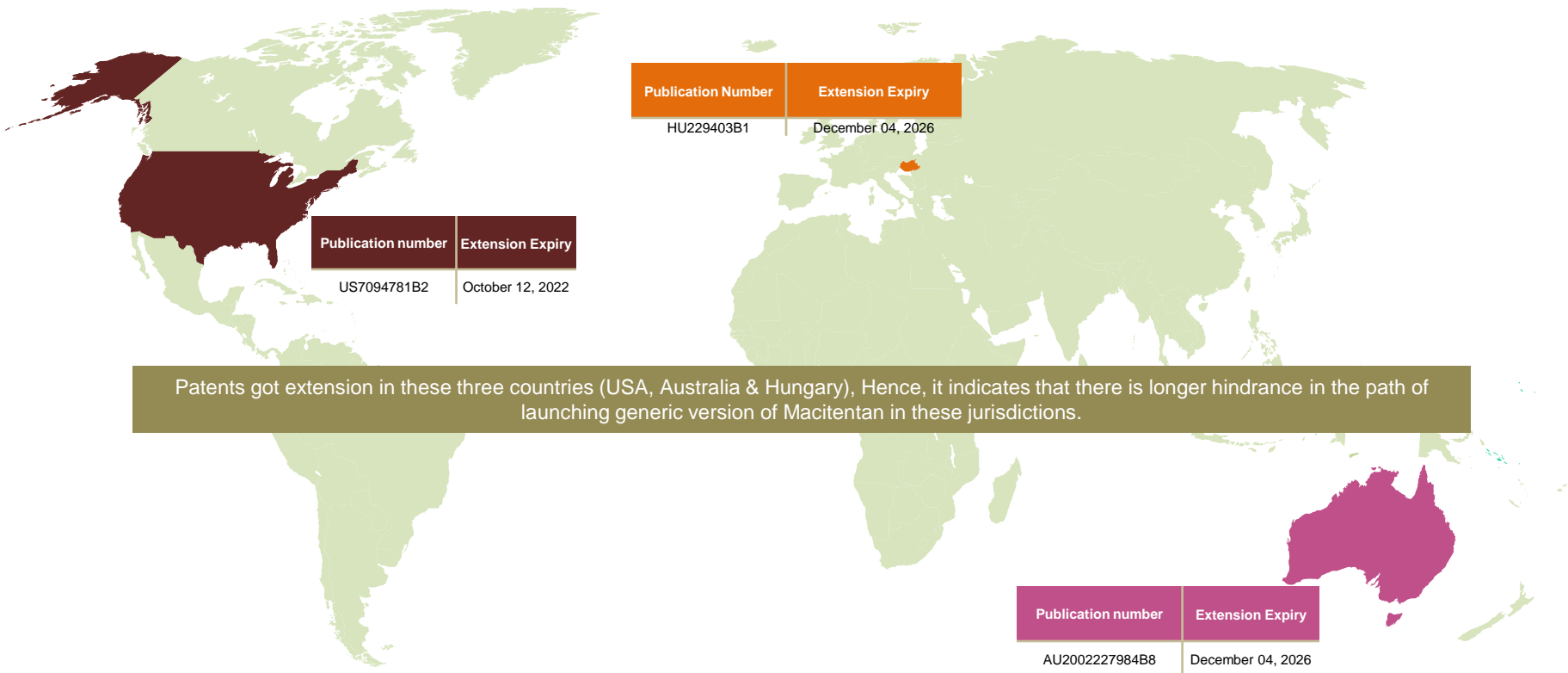
Patent has INPADOC Family members filed in 23 countries.

23 Countries where Macitentan (API) is being protected

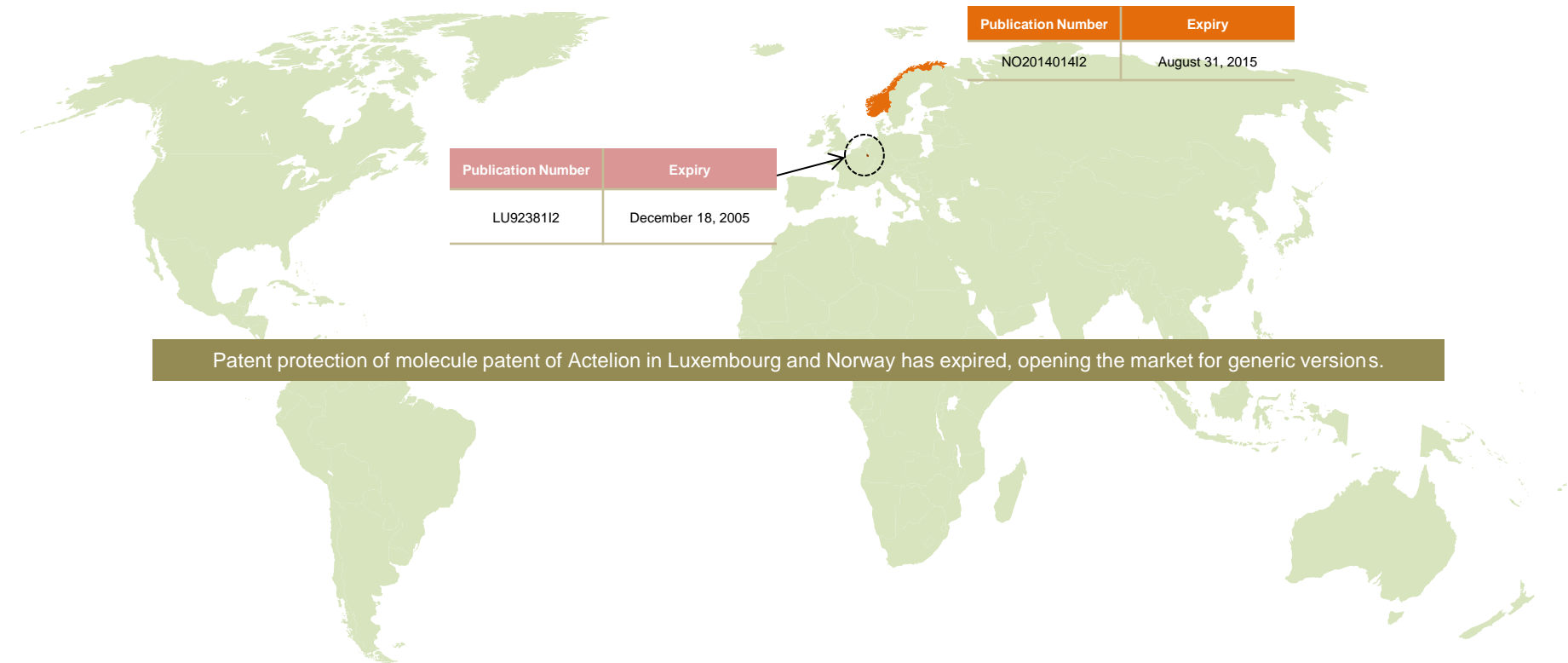


Note : The references are INPADOC family members of Key patent (US7094781) assigned to Actelion for Macitentan.

Three Countries where Macitentan is being protected for longer time



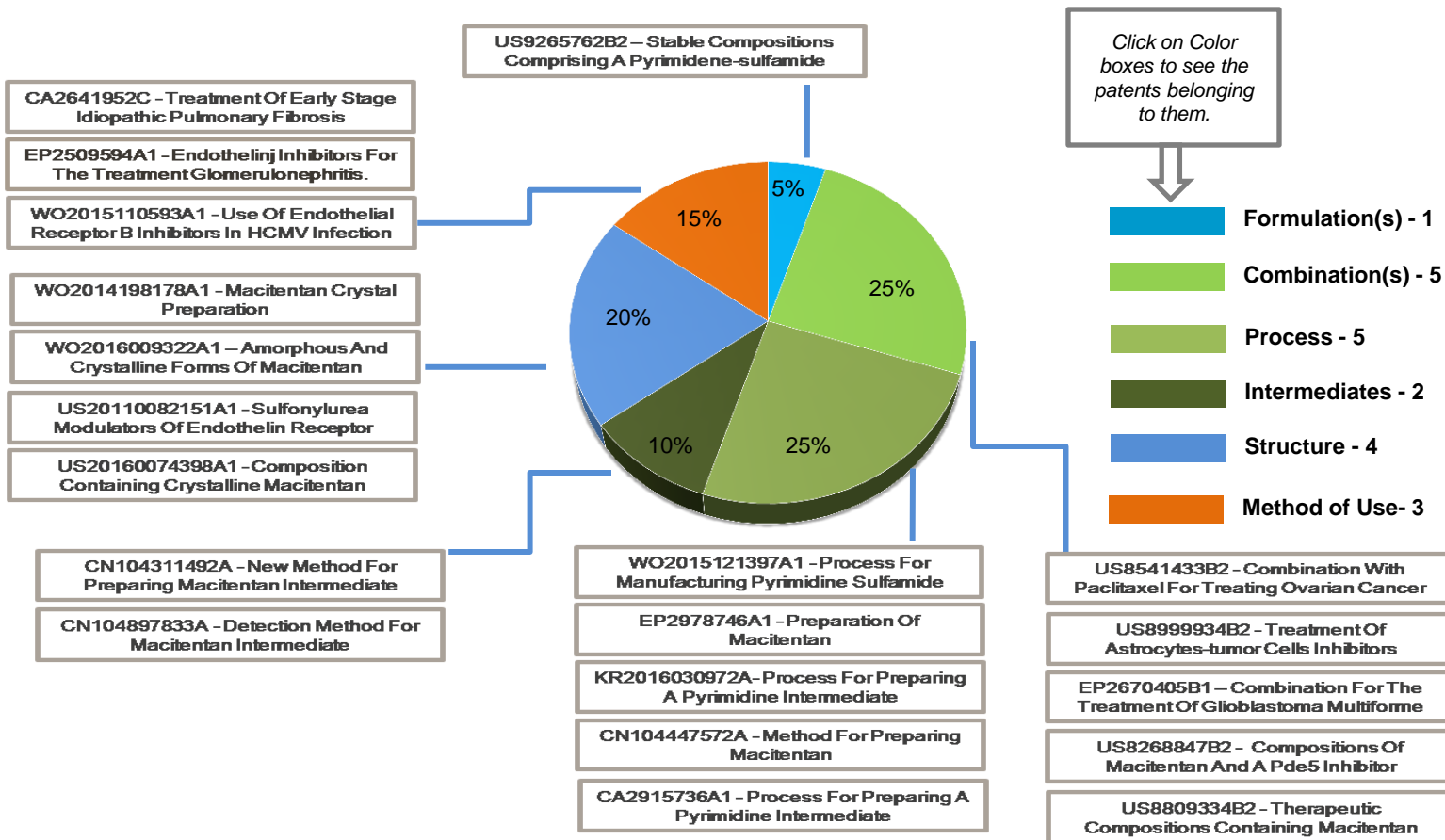
Patents got extension in these three countries (USA, Australia & Hungary), Hence, it indicates that there is longer hindrance in the path of launching generic version of Macitentan in these jurisdictions.



Are there other patents related to Macitentan which would still be in effect after the expiration of the key patent?

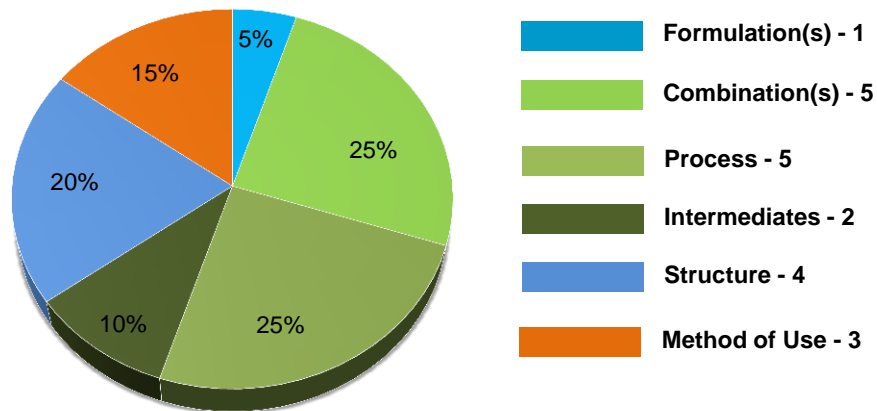


Patent category distribution on the basis of features



Patent category distribution on the basis of features

- Most of the 'Method of use' patent relates to other companies disclosing development of Endothelin receptor antagonist in treating other diseases.
- There are few attempts by Acetelion to protect the extension of indication of Macitentan in the treatment of Pulmonary fibrosis.



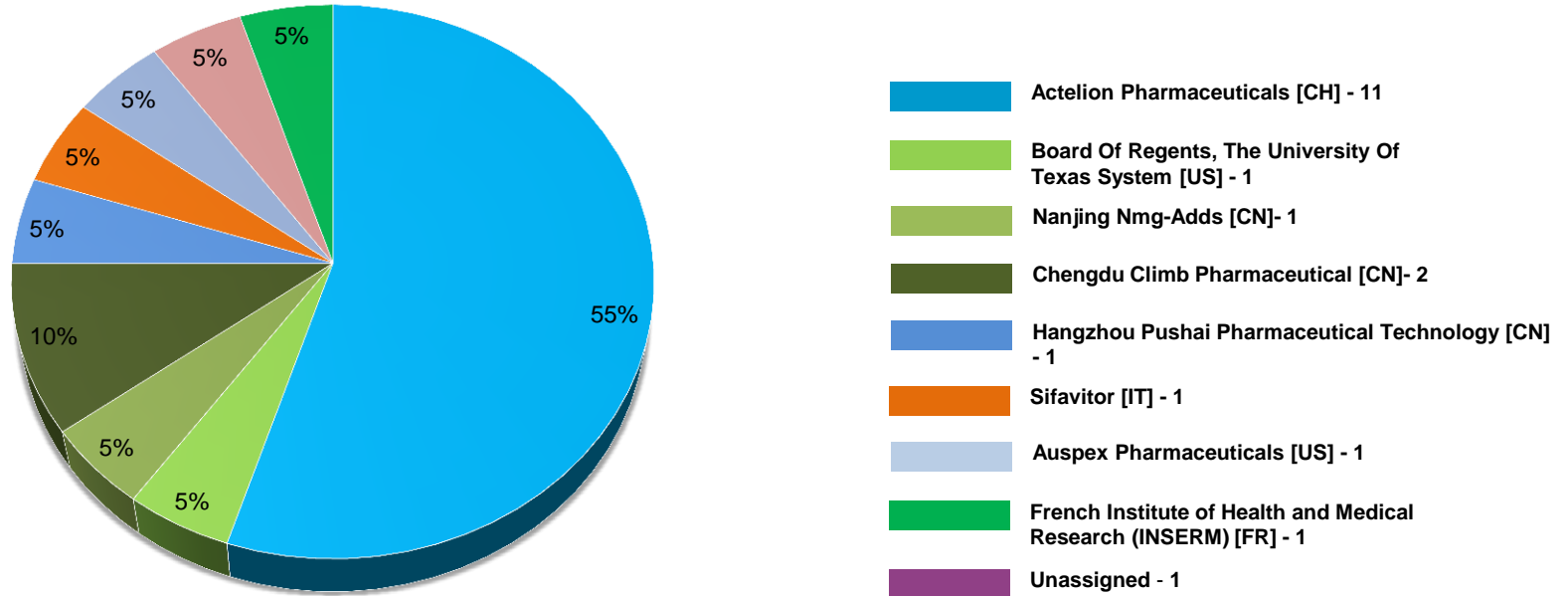
- Amongst the 'Structure' patents, there have been some attempts by generic companies to circumvent and develop technologies for different crystalline or amorphous structure of Macitentan. Similarly, Sandoz has published a patent [US20160074398A1](#), disclosing the polymorph of Macitentan.
- As so many companies are filing patent in this domain. Hence, there might be the potential that generic company might launch its products by filing patents on polymorphs.

What could future threats for Generics if they venture into preparing generic drugs related to Macitentan?



Future threats for Generics

- Actelion is clearly the most dominant player, responsible for a moderate proportion of the filings with a 52% share of the patent landscape while the rest of applicants account for only 48%.
- Auspex, acquired by Teva pharmaceutical ([Source](#)), filed 1 patent that is relevant to the Macitentan molecule. This indicates that Teva may be interested in launching generic version of Macitentan, which may give tough competition in future.



Note: The numbers in front of Company's name represent unique patent families.

What else can we find out in a 'Drug-specific' patent analysis?

This report is just a 'snapshot' of the 'Patents covering Macitentan' and intends to provide the reader with preliminary idea on the upcoming patent expirations and business opportunities for a generics manufacturer. This research can be fine-tuned to reveal more in-depth and detailed insights into the industry based on patent and market data. If you liked our preview, here is a few examples of what more you can get-

Which are the protected features in patents to be avoided by R & D to launch generic version?

What could be the options for launching a generic version before expiry of the key patent?

Who are the entities publishing non-patent research literature on a Drug?

Which are the alternates to the Drug (in-focus), which have a growing market share?

Which companies should you keep an eye on ?

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