Oppositions

A business perspective focusing on reasons, tactics and usefulness of oppositions: before, during and after filing

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Agenda

Project: Xgliptin, a DPP-IV inhibitor (Diabetes)

1. Project and importance
2. Competition fierce
3. Internal pressure
4. FTO (Freedom to operate) issue: Opposition filed
5. Confident patent dept. vs. Nervous top mgmt
6. Timing and initiating licensing opportunity
7. Teamwork, teamwork, teamwork

Xgliptin

Xgliptin and importance

1 Xgliptin was aimed to be a blockbuster and an important successor to a current blockbuster close to expiry with annual sales around 6 billion USD. Inhibitors of dipeptidyl peptidase 4, called DPP-4 inhibitors or gliptins, are a class of oral hypoglycemics that block DPP-4. They can be used to treat diabetes mellitus type 2. Glucagon increases blood glucose levels, and DPP-4 inhibitors reduce glucagon and blood glucose levels.

Competition fierce

2 Company Y and Z had similar projects in the pipeline. Unfortunately, they were way ahead in drug development. In the primary care business it is important to come first with a breakthrough medicament. Although it was believed that Xgliptin has a better patient profile as the competition, being first is essential.

Xgliptin

Internal pressure

3 Due to the earlier competitor projects, company X started a program to accelerate the clinical and regulatory programs. This has to be a success. Resources and money were brought in to ensure compliance to the timelines.
At the scientific and commercial meetings there was a culture of 'whatever it takes we will beat competition'

FTO analysis: Dominant Patent right

4 Xgliptin, but also the competitor's gliptins were found to be within the scope of a US and EP patent owned by PBD. Company Y (but not Z) already took a (early) license but Company X was of the opinion that the patent estate was invalid and therefore no FTO-issue was apparent. Company X (but also others) filed a notice of opposition at the EPO. The written proceedings at the EPO were moving to oral hearings, scheduled shortly (2004). Although, the Patent department of Company X (and consequently all project team members of Xgliptin) were still convinced that the patent estate of PBD was invalid, some residual risk would be inherent and communicated

Xgliptin

Promising project

1 Need for successful successor for current blockbuster.

Residual risk to be blocked by method patent

2 Patent owner was not active in drug development and had no candidate DPP-IV inhibitor. But Company Y took a license.

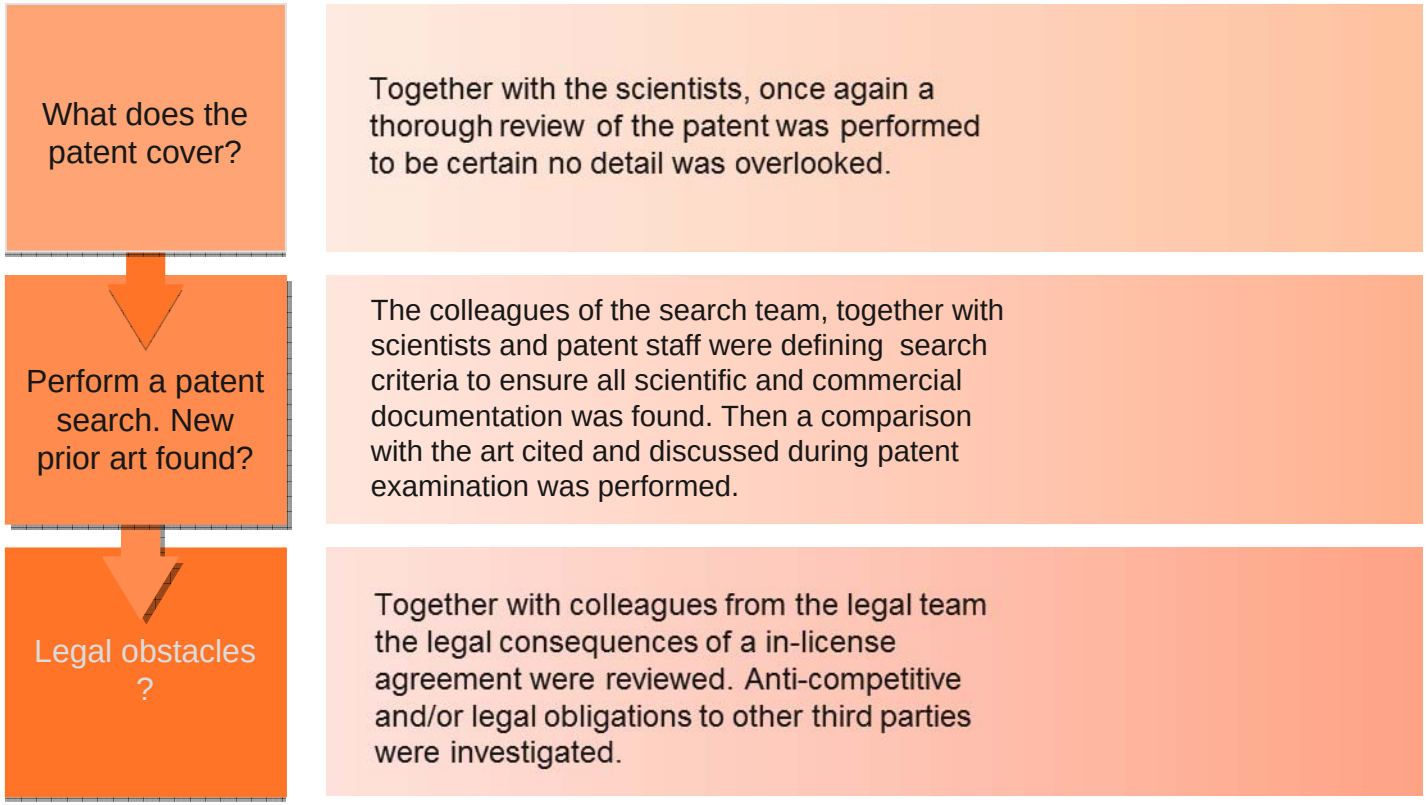
Oral hearings at EPO scheduled shortly

3 There has been (many years ago) an initial contact made by scientists of Company X for a license with negative reaction.

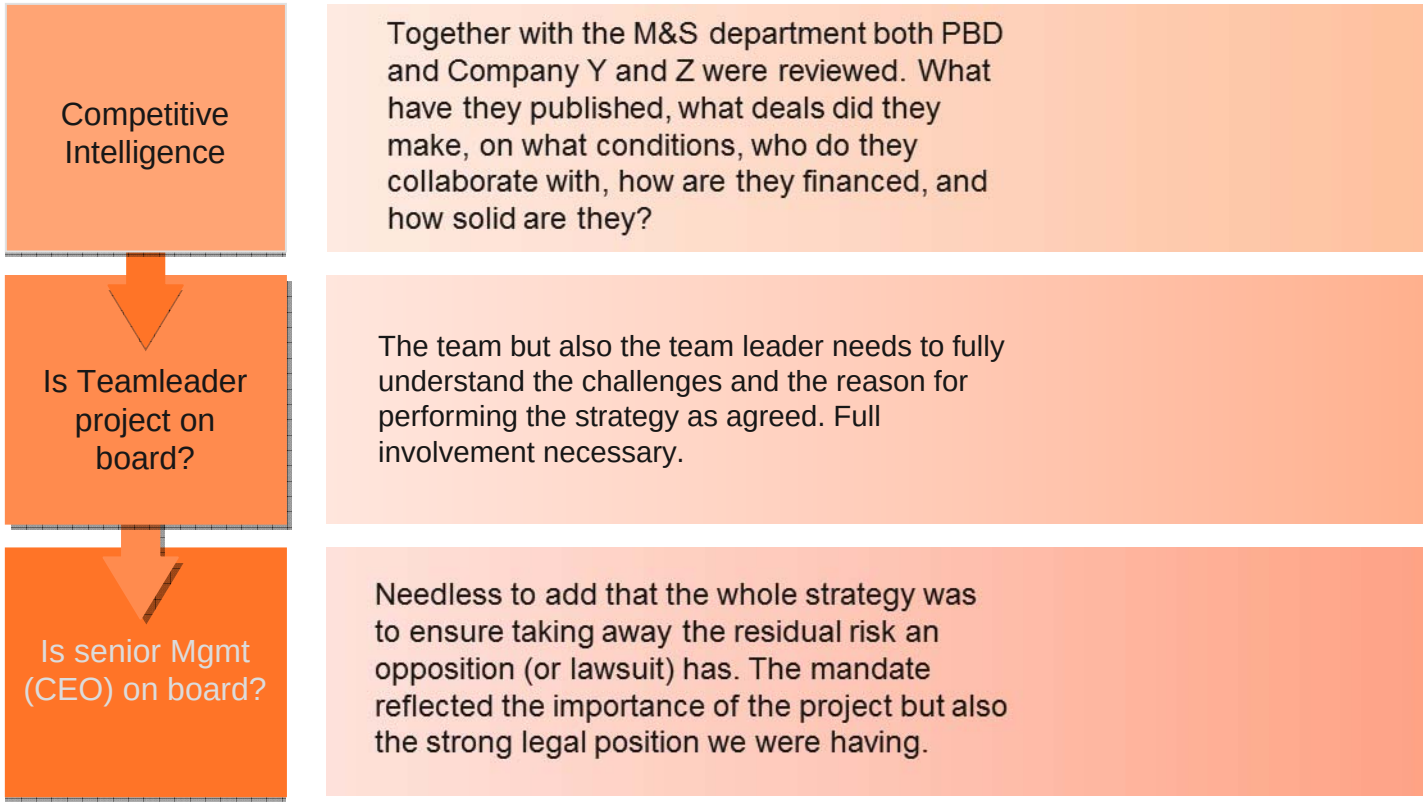
After a discussion with the Head of Marketing, and reviewing the patent situation with the responsible patent attorney we concluded:
-To explain to senior Mgmt the situation,
-To approach PBD to initiate a discussion,
-To seek a negotiation mandate,
-To plan a negotiation strategy.

Xgliptin

Patent Review: Due Diligence



Xgliptin
Patent Review: Due Diligence



Xgliptin

Response PBD

1 After our DD (performed within 2 weeks) we approached PBD on Friday afternoon knowing the oral hearing was scheduled for next Monday morning 9.00 am. After indicating the win-win situation they agreed to talk.

Negotiation process

2 On Sunday afternoon 2 pm the negotiation team (legal, patents, R&D) started to talk. After many breaks and even more coffee we found a mutual acceptable agreement on Monday morning 8.00 am. We notified the Opposition Division at 9.00 am that we would withdraw from the proceedings leaving the other opponents behind in a state of shock.

Result

3 The reached agreement did ensure there were no obstacles for a speedy launch of Xgliptin. The price paid was in no way damaging the forecasted sales. Eventually, four years later the patent was revoked. Due to clinical issues Xgliptin never became a real successor of the current blockbuster.

Xgliptin
Lessons learned

Teamwork is key. Scientific, patent, legal and commercial interaction.

Transparent expectation management is needed.

In all phases the right people should be involved.

Proper review of the patent estate, understanding the need for the license, reviewing alternative processes, being open-minded and sensing the business requirements will bring you to a successful result.

Lessons learned or Take-aways

Pre-opposition phase

1. Thorough review of problem patent
2. Does filing an opposition solve this problem?
3. Are there alternatives for solving the problem?
4. Who benefits from filing the opposition?
5. Is time spent during opposition procedure helpful?

Lessons learned or Take-aways

During opposition phase

1. Sole opponent or more?
2. Collaborate with other opponents to strengthen case?
3. Considering continuation or settlement?
4. Ongoing review of opposition strategy during process? Have parties changed (acquisitions, mergers, …)

Lessons learned or Take-aways

Pharma specific

1. Big pharma companies do not prefer oppositions (exceptions exist). Who is biggest patent validity threat?
2. Oppositions after grant of patent and years before pharma product launch. Good or bad?
3. Licensing almost always possible if you are not a direct threat
4. Licensing ends dispute and is inter-parties. No-one will know the exact details other than the parties.

Thank you

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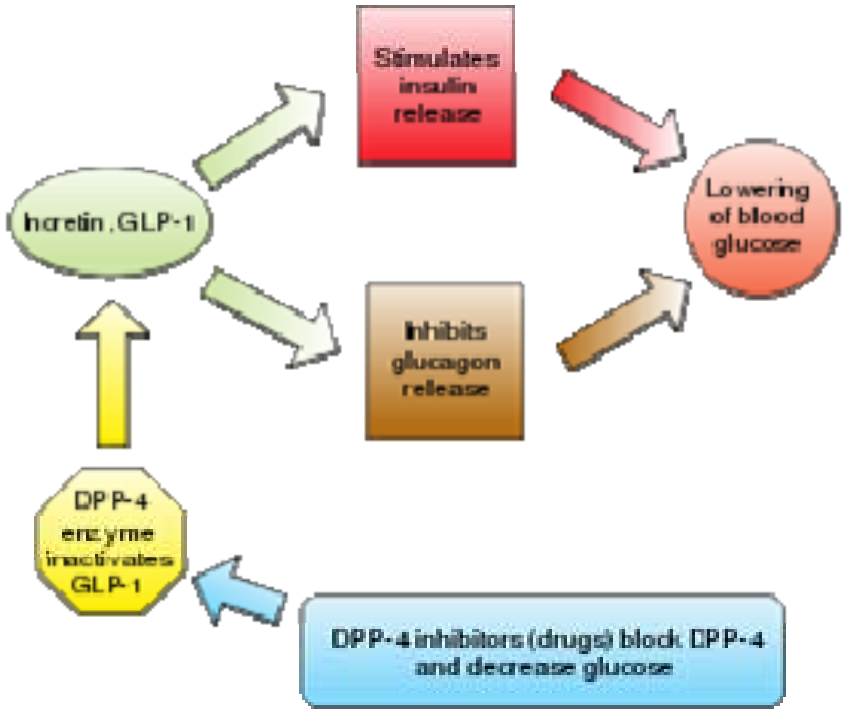
Xgliptin

Science: Mechanism DPP-IV Inhibition



Xgliptin

Patent PBD: Scope EP Patent

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P IV-
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Claims

1. The use of activity lowering effectors of dipeptidyl peptidase IV (DP IV) or DP IV-like enzyme activity for the preparation of a medicament for the oral therapy of diseases which are based on glucose concentrations in the serum of mammals characteristic of hyperglycemia.

2. The use according to claim 1 for the preparation of a medicament for the prevention or alleviation of pathological abnormalities of the metabolism of mammals such as glucosuria, hyperlipidemia, metabolic acidosis and Diabetes *mellitus*.