EIP

What should you look to protect in a (bio)pharma IP strategy?

Potential investors and development partners will expect to see an IP portfolio and strategy which maximises protection for the assets under development.

Protect the active(s)

The most important filing in any (bio)pharma IP portfolio is that which covers the new chemical or biological entity (NCE or NBE, respectively) or, in some cases, covers a new combination of APIs (where that is the invention). Generally this key filing is drafted with a broader, generic claim which covers all of the examples for which you have data (or will soon generate data), and some scope around these (in an attempt to keep third parties away from the space).

Ideally the lead(s) are exemplified in the first filing, with data. However, if this is not the case, or if subsequent work identifies a new lead (replacement or 2nd gen product), further filings directed to the NCE or NBE may be possible and often are necessary.

Yet further filings directed to NCEs or NBEs may be advisable as defensive filings – these cover areas which do not include your lead or cover your primary area of interest, but could cover a back-up compound, or simply be used to stop third parties operating in a near space.

Secondary filings

Secondary filings are a useful way to extend monopoly protection as much as possible.

If timed well, they can extend patent lifetime and market exclusivity – immediately elevating the investment potential. Ultimately, the product needs to generate a return on investment, and a longer period without competition from generics can only increase the chances of a positive return.

Depending on the development point, a strong IP portfolio will have filed applications (or have planned filings in the IP strategy) which cover one or more of:

- Formulation – particularly where preparing the API, at the required concentration, in an appropriate formulation (e.g. tablet, solution, parenteral, topical etc.) is difficult, or where a particular formulation provides an unexpected advantage such as improved stability, pharmacokinetics and/or pharmacodynamics.
- Polymorph – particularly where a given polymorph provides unexpected advantages, such as solubility/bioavailability etc.
- Synthetic route and intermediates – this protection is particularly valuable if you can protect all commercially viable synthetic routes, and the intermediate compounds along the way.
- New indication or patient group – if the API is found to be particularly suitable for a particular patient group or indication, this can be protected. This can effectively protect your USP and key market.
- Dosage regime – similarly, protecting an advantageous dosage regime can also effectively protect your USP and key market.

Some of these can be as valuable as the NCE/NBE filing, if they protect the only commercially viable product; whilst third parties would in principle be able to use the API following lapse of the main filing, if there is no commercially viable route to do so, the secondary filings can provide an extension on the absolute monopoly for the active.

Timing of filings directed to a new indication or patient group, or a new dosage regime, must be carefully pegged against clinical trial timelines to ensure that the protection sought is robust. If the timing is wrong, it is quite possible to find that your patent application is insufficiently substantiated (and will not be allowed), or is not patentable in view of your own published clinical trial protocols.

IP strategy should be part of your overall business strategy. Patent filings (existing and future) need to be timed appropriately to maximise protection; factors such as planned clinical trial dates feed into a good IP strategy, and investors and partners will expect to see the scientific and commercial angles of the business operating together. Our

Stratiphy offering works with you to ensure that your IP strategy is a key pillar of your overall business plan, maximising your investment potential and enterprise value.