
ExtendiP
Potter Clarkson
28 tablets
(4x7 s)
Tanzaril
MADIPLOT
20 mg tablets
NOVARTIS
POTTERCLARKSON.COM

Extend your patents' terms. Extend your exclusivity. **Extend*iP***.

Pharmaceuticals improve and extend the lives of millions of people.

However, to get a drug to the stage where it successfully fulfils its clinical purpose requires a huge amount of investment, research, development, and strategy.

A pivotal part of this is deciding how best to maintain your exclusivity in the market.

Maximising your exclusivity is essential. It's how a pharmaceutical company realises a return on investment by excluding competitors from the market for as long as possible.

Drug development takes years and is resource intensive. It requires a large team of highly specialised professionals. Most of all, taking a new drug from concept to regulatory approval requires an enormous budget.

Even then, there's no guarantee your drug will ever reach the approval stage. This is why extending your exclusivity for the maximum possible term is essential.

By working in tandem with informed pricing and a solid IP strategy, making use of all the available tools to prolong exclusivity, you can maximise the chances of your drug becoming a financially viable asset.

But if there's any opportunity left open for competitors to flood the market with their own version of your hard work, this won't happen. Contrary to what some people say, exclusivity is not all about profit.

It's about preserving revenues that can be reinvested to further improve our well-being by funding a pipeline of new and better drugs.

How can you extend your drug's exclusivity?

A patent will give your drug an initial 20 years' exclusivity.

However, in most cases, the lion's share will be taken up by working to obtain the regulatory approval you need to take your drug to market.

In this case, your primary aim must be to offset the portion of your patent's life that has been lost during the extensive testing and trial processes you have undertaken.

If you were to lose your exclusivity upon patent expiry, you run the risk of your competitors producing alternative versions of your drug that will compete with it directly. It's therefore essential to leverage all the tools available to you to prolong your exclusivity beyond patent expiry for as long as possible.

By working through this process with an experienced patent attorney, you'll receive a comprehensive analysis of your current situation. They'll ensure you are in the best possible position to take full advantage of the various patent term extension options and data and market exclusivity tools open to you. We call these options/tools "regulatory IP" and they include:

SUPPLEMENTARY PROTECTION CERTIFICATES

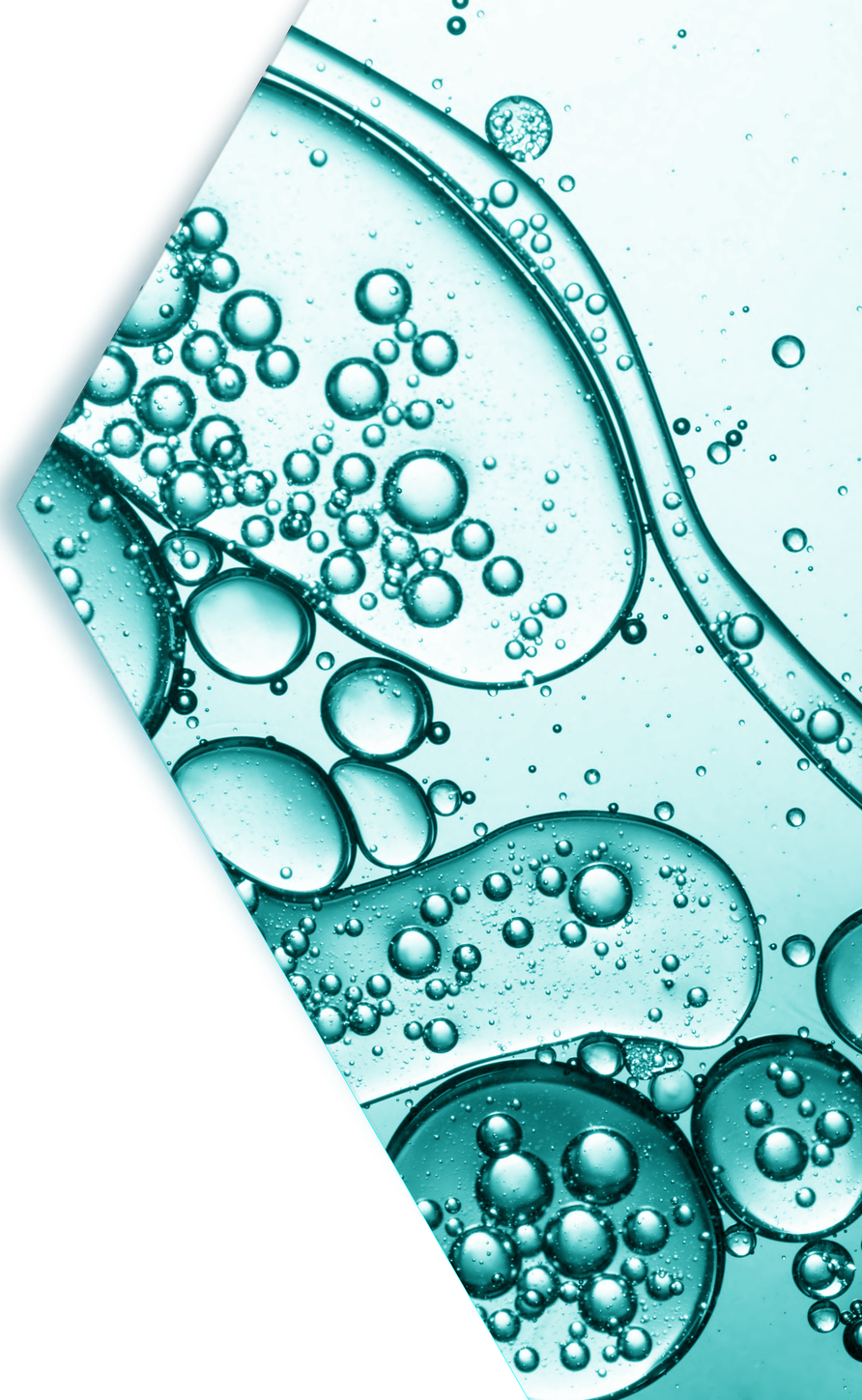
A supplementary protection certificate (SPC) is an intellectual property right that will extend your patent for a maximum of five years.

It’s available in the UK, all EU member states, Switzerland, Norway, Iceland and some other European countries.

PAEDIATRIC EXTENSIONS

You may be able to extend your SPC for a further six months with a paediatric extension. As with SPCs, paediatric extensions are available in the UK, all EU member states, Switzerland, Norway, Iceland and some other European countries.

To obtain a paediatric extension you will need to have conducted clinical trials in a paediatric population in accordance with a paediatric investigation plan (PIP).



PATENT TERM EXTENSIONS IN OTHER TERRITORIES

It is possible to extend the term of patents relating to drug products in other territories, including Australia, China, Israel, Japan, Russia, South Korea, Taiwan and the USA.

As with SPCs, the general idea is to compensate for regulatory delays, but there are some country-specific differences in terms of the products that qualify, the length of the extension, and the scope of protection.

DATA AND MARKETING EXCLUSIVITY

As the regulation process demands a substantial volume of clinical trial data, protecting the data you have is extremely important; you don't want competitors taking commercial advantage of your hard work.

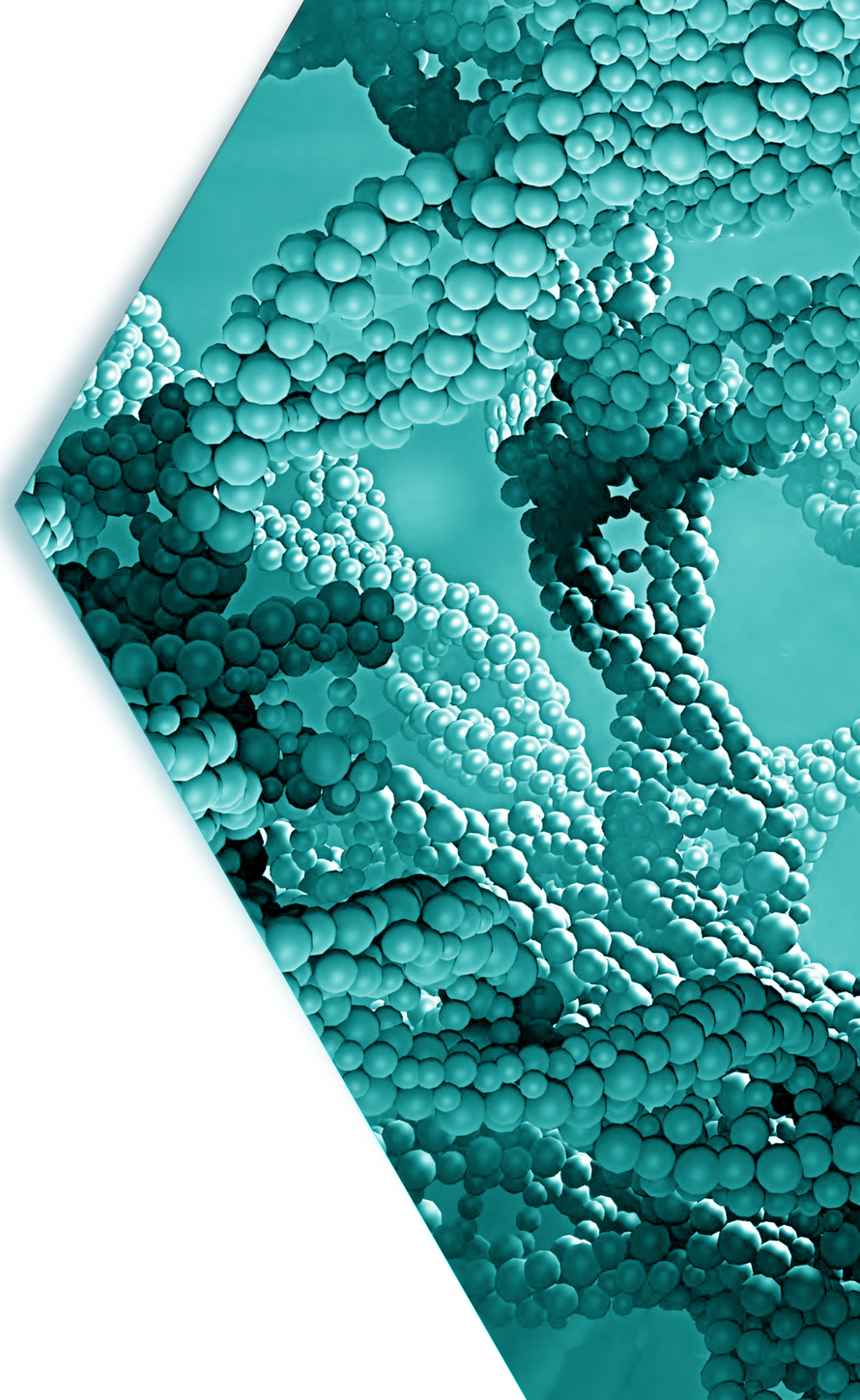
Data exclusivity refers to the period during which a generic company cannot rely on your clinical trial data to show that a drug is safe and effective.

Given the significant financial investment you have made to generate your data, this creates an important entry barrier and hence a source of market exclusivity independent of patent protection.

In Europe, 8 years of data exclusivity are available followed by a further 2 years of marketing exclusivity, during which time a generic company is still barred from marketing their product although they may now rely on your data to apply for an authorisation.

In addition, you may be able to obtain an additional one-year of exclusivity if you find a new therapeutic use for your drug.

Data and marketing exclusivity are only available for new active ingredients and new fixed dose combinations of approved drugs. However, if a particular form of a known active ingredient under development is found to have improved safety and/or efficacy, it may be possible to classify it as a new active ingredient, thereby benefiting from a new period of data and marketing exclusivity.



ORPHAN MEDICINES AND PAEDIATRIC INCENTIVES

Further exclusivity periods are also provided to stimulate research into orphan and paediatric indications.

‘Orphan drugs’ are drugs that treat diseases so rare the cost of their development would hugely outweigh the revenue they’d generate.

However, if it can be shown that your drug offers sufferers a way to diagnose, treat or prevent a rare disease, it could be entitled to an additional 10 years of market exclusivity. (This could be reduced to six years if there is evidence your drug is too profitable to justify its orphan status at the end of year five.)

Market exclusivity awarded for an orphan indication is separate to the standard data and marketing exclusivity periods and runs parallel to other exclusivities if they overlap. A medicine with several separate orphan designations for different indications can be awarded separate market exclusivities if they are to separate designated conditions.

There may also be exclusivity incentives available for carrying out clinical trials in the paediatric population. For example, it may be possible to increase your orphan market exclusivity by a further two years if further paediatric studies are performed.

Similarly, it may be possible to extend the standard data and marketing exclusivity period by one year if a new therapeutic indication is found based on paediatric studies.

However, such exclusivities are not available if the paediatric studies are used to secure a six-month extension of an SPC, and so decisions need to be made about which incentives to secure.

Why do you need to establish a conclusive and comprehensive exclusivity strategy?

Once your new drug is approaching the final stages of regulatory approval you need to do everything you can to extend its exclusivity.

The longer the period of exclusivity you can secure, the more time you will have to recoup your investment and maximise revenues.

When it comes to extending the potential period of exclusivity for your drug, there are several options to consider. Taking full advantage of each option in the different jurisdictions in which you plan to sell your drugs will require a number of business-critical decisions.

Your choice of options and your decisions as to how you want to use them will form the basis of your exclusivity strategy and your immediate action plan.

Your strategy should also reflect the three different sources of exclusivity in Europe, arising from the patent, SPC and regulatory legal frameworks. It should show exactly how these three sources will overlap and interact to ensure your drug is awarded the maximum period of exclusivity.

However, given the financial implications, your exclusivity strategy should always be based on a comprehensive analysis of both your current circumstances and commercial objectives, supported by impartial advice from an experienced pharmaceutical sector specialist.

If you are in close communication with your IP attorneys and regulatory consultants during the research and development process, you'll have formulated your exclusivity strategy during your regular discussions.

But, as the end of your patent's life approaches, it may be time to reassess where you are, reconfirm you are ready to take advantage of the extensions that are available and obtain any additional IP rights you may need.

You can't afford to leave any cracks in your protection that could be exploited by your generic competition, allowing them to enter the market you've worked so hard to create.

It is therefore important you take a step back and:

- Analyse your current exclusivity position (patents and "regulatory IP").
- Consider if there are any additional tools you are able to utilise (e.g. PTEs) and understand how to obtain them.
- Understand how your patent exclusivity maps to your regulatory exclusivity.
- Weigh up the respective scope and expiry dates each option offers against current competitor activity so you can make your final decisions based on value.

This is where Extend*iP* will help.

How does **Extend*iP*** work?

As you approach the final stages of the regulatory approval process and it looks as though your drug will be approved in the EU, US, and your other key territories, we'll conduct a thorough exclusivity audit to identify how best to extend the term of your patent and maintain your exclusivity for as long as possible.

We'll examine the current circumstances surrounding your patent portfolio and the ongoing regulatory procedures in detail.

We'll determine if it is possible to extend term of any of your patents and highlight the data and marketing exclusivity periods that could apply.

We'll recommend the course of action we'd take if we were in your shoes.

We'll set out a clear, structured action plan outlining the required steps and deadlines for you to follow.

At the end of the process, we'll produce a succinct report that sets out our findings and a clear and structured strategy we'd suggest you implement to prolong your exclusivity.

To ensure our analysis delivers as much value as possible, we break down our findings to map out the scope and timeline of the various exclusivities (patent and data/ marketing exclusivities) so you know exactly how you are protected and until when.

Our analysis will be supported by our recommendations as to how you can use everything we uncover to extend your exclusivity and maximise the commercial value of your innovations.

If required, we can also present our findings (either in person or virtually) to give you and your team an opportunity to ask questions about both our findings and our recommendations.

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