

Risk of SPC waiver counterattack makes generics extra cautious

Rory O'Neill July 21, 2022



The EU's landmark SPC waiver has taken full effect, but generics still have plenty of legal obstacles to navigate

Generic industry reps were in a bullish mood at the start of this month when the EU's supplementary protection certificate manufacturing waiver took full effect.

But their optimism was tapered with caution.

On July 1, the day the waiver's transitional period ended, representative organisation [Medicines for Europe](#) remarked that the legislation shouldn't be misused by innovators to block competition.

More specifically, it urged courts to reject originator efforts to access generic and biosimilar makers' commercially sensitive information.

That note of caution reflected an industry concern that the waiver could be something of a double-edged sword.

Under the waiver, generics need to give SPC holders at least three months' notice if they plan to manufacture or stockpile certificate protected products.

Managing IP spoke to in-house counsel and private practice litigators on both sides of the pharma divide to learn more about their plans for this provision.

Both sides agree it's a tricky point for generics to navigate, and it could even lead to an increase in secondary patent infringement litigation.

SPCs are typically used by innovators to extend the life of key patents, such as those covering the composition of matter.

But originators generally hold many more patents covering features such as manufacturing processes or dosage regimens.

Some originators say they could use the info provided by generics to help build infringement cases with their non-SPC-protected inventions.

“You could put out the flame while it’s starting, before it goes into full blast,” says the senior patent counsel at one biologics maker.

The head of intellectual property at one European generics maker says that a risk the company is factoring into their strategic discussions.

“We will need to be even more careful in our analysis of a patent owner’s portfolio than we were before, otherwise an SPC holder could take advantage,” the source says.

To make matters even less clear, it’s not certain exactly what information generics makers need to give originators.

That lack of knowledge is likely to form the basis of litigation at the Court of Justice of the EU, predicts Marco Stief, partner and head of legal at Maiwald in Munich.

“It could take at least 10 years before we have enough case law to fill in the gaps and ambiguities in the regulation,” he says.

Double-edged sword

The big decision for generics will be whether they can afford to let rivals know what they’re up to.

It’s normally very difficult for an originator to find out if a generic maker has started to manufacture a version of its product or about the supply chain, says Laura Orlando, partner and global head of IP at Herbert Smith Freehills (HSF) in Milan.

Orlando, who has worked extensively with originators, says the waiver’s three month notice requirement could make it easier for rights owners to monitor generics’ activity.

“Our biggest challenge is normally finding out infringement has started before the generic comes to market,” she says.

By handing over at least some of that info, generics could open themselves up to lawsuits over patents that don't fall under the waiver, adds Robin Ellis, partner at Reddie & Grose in Munich and former in-house counsel at Sandoz.

"In practice, it could be a double-edged sword for generics and biosimilar makers," Ellis says.

The senior biologics patent counsel points out that the new Unified Patent Court (UPC) will be able to order inspections of premises if there is evidence of infringement.

"It might change the game a bit," he says. "It gives you the hook to make infringement easier to prove and injunctions easier to get," he adds.

Orlando of HSF adds that inspection orders are quite easy to get in Italy and are available in France and Belgium too.

"We don't know what the threshold for an inspection order at the UPC will be yet," she says.

Ellis says originators going down that route will likely meet legal resistance from generics.

"There's an argument that it would be anti-competitive for a patent owner to use the info in the notification to enforce secondary patents," he says.

But originators will also take a risk if their secondary patents aren't very strongest, adds the UK-based head of IP at one generic maker.

"Originators don't want to be forced to litigate rubbish patents early," he says. "They may resolve issues as soon as possible for the sake of certainty, rather than in the heat of a day one launch."

The senior biologics counsel agrees there are downsides to relying on dosage and second medical use patents in infringement litigation.

"A lot of European courts are cracking down on those patents when they're litigated. They're often invalidated," he says.

Proceed with caution

Generic makers who want to use the system face a delicate balancing act – and Stief of Maiwald is doubtful many will want to take the risk.

“The system entails considerable risks for generics, because they’re more or less admitting to patent infringement,” he says.

“I know of several companies thinking about whether to file one, but I haven’t yet seen any evidence of widespread use of the system,” he says.

Ellis says he only knows of one manufacturer that has applied to use the waiver so far.

The generics head of IP agrees it will be vital for generics to do their homework before using the new system.

“You need to ensure you have a very clean product with no grey areas in terms of patents before deciding to notify,” he says.

Beatriz Díaz de Escauriaza, head of IP at Insud Pharma in Madrid is optimistic about the waiver and says the sector still broadly welcomed it with open arms.

“There are uncertainties because it’s a new system, but they won’t preclude us from using it.

“We will make sure we’re coordinated internally so that we properly comply with the waiver and avoid any possible risks,” she adds.

The danger will be much greater when notifying of intention to manufacture for a day-one launch in the EU than for export, she adds.

We’ll learn more about waiver strategy in the coming months but, for the moment, caution is essential.

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