

EIP

To Injunct Or Not To Injunct?

Judge Asked To Grant A 9/10 Day Interim Injunction to Protect Bayer's Anticoagulant Rivaroxaban Ahead of Main Judgment

Pharmaceutical company, Bayer found success in its application seeking an interim injunction, lasting just 9-10 days, to protect its rivaroxaban product from the generic companies it is currently embroiled in litigation with whilst awaiting judgment on its patent covering rivaroxaban.

Background

This case revolves around rivaroxaban. Rivaroxaban is one of several direct oral anticoagulants available for prescription. Bayer own two patents that cover rivaroxaban. The first patent protects rivaroxaban as a compound. That patent was extended by an SPC until 1 April 2024. Up until 1 April 2024, Bayer have had the rivaroxaban market to itself, selling the product under its brand name Xarelto. Therefore, as of 2 April 2024 others would be entitled to market rivaroxaban. The second patent, EP(UK) 1 845 961 ("EP 961"), in broad terms, covers the use of rivaroxaban for the manufacture of tablets for once-daily oral administration to a human patient. EP 961 expires in January 2026.

EP 961 has been subject to six actions for revocation which were joined, with the trial heard earlier this year. At trial, the Judge told the parties that judgment would be handed down in the first week of the Easter term, and in all likelihood probably on 9 April 2024, with the form of order hearing to be on the 11 or 12 April 2024. This meant that a window of 9-10 days arose whereby the compound patent would have expired but there was a possibility of a permanent injunction against the respondents restraining sales of once-daily rivaroxaban in the event that EP 961 was held valid. Bayer's application before the Judge was to ensure that this window was kept shut until judgment on the EP 961.

The Applications Before the Court

The court had four applications before it. This article focuses on Bayer's aforementioned application seeking an interim injunction against parties it is in litigation over the rivaroxaban product.

Communication with the Court

The Judge was critical about the parties' communication with the court in relaying the consequence of not handing down his judgment until 9-10 days after 1 April 2024. The Judge recounted that the various claims filed with the court and eventually joined were progressed "without unusual haste". On the first day of trial, the claimants' counsel had stated that the claims had been case managed together so as to try to ensure that judgment could be handed down before 1 April 2024 but the Judge did not recall any information being provided about the consequence of not achieving that. Therefore, he was surprised at the scale of the interim application including the number of counsel and solicitors involved. The Judge wondered whether the deep involvement of the legal advisers meant that they had assumed everyone was clear on the significance of judgment not being handed down in time for argument on the form of order by 1 April. The Judge made it clear that he was not aware of said consequence and that had the parties communicated the issue to the Judge, the court would be in a better position to give the matter appropriate priority. He surmised that "in short, better communication with the court is desirable."

Bayer's Interim Injunction Application

The Court applied the well-known American Cyanamid principles when looking to assess the suitability of granting or rejecting Bayer's application for an interim injunction. The parties agreed that there was a serious question to be tried which had been a question before the Court at trial and would be answered with an imminent judgment. In this case of the interim injunction, the issue between the parties concerned the balance of

irreparable harm.

p3

Additionally, the Judge used the Court of Appeal's judgment in *Neurim Pharmaceuticals (1991) Limited v Generics (UK) Limited* [2022] EWCA Civ 370 for guidance as to the correct approach given that there was some overlap in the facts.

Decision

Due to the short time that this interim injunction would be in place, the Judge was not completely convinced that both parties would suffer irreparable harm. The Judge felt that Bayer's lost sales could be calculated easily given that their current sales were known and that they were the only ones on the market with rivaroxaban. And although there may be uncertainties that may not be quantifiable, the Judge hypothesised that these would be modest. With the respondents, the Judge was also convinced that their loss of sales could be calculated with an area under the curve calculation. The Judge suggested that a graph of each of the respondents' sales could be notionally moved back by 9-10 days or by whichever time that the evidence may suggest is appropriate. But looking at the Court of Appeal and its emphasis on the importance of maintaining the status quo in circumstances such as those in the application before him, the Judge believed it more appropriate to grant the interim injunction until resolution of the order to be made following the imminent hand down of the judgment on the EP 961.

Take Away Points

A key point arising from this judgment is that communication with the Court is of utmost importance. Not only can it avoid potential wasted costs but it can also bring to the forefront any urgent issues that need addressing or that may have consequences if matters are not concluded within a certain timespan. It is easy to forget that the Court has not lived through the case and so cannot be assumed to appreciate matters which the parties have at the forefront of their minds.

The judgment is available [here](#).