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HP-2022-000032  
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HP-2024-000002

**IN THE HIGH COURT OF JUSTICE**  
**CHANCERY DIVISION**  
**BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES**  
**PATENTS COURT**

Royal Courts of Justice, Rolls Building  
Fetter Lane, London, EC4A 1NL

Date: 27 March 2024

Before :

**HIS HONOUR JUDGE HACON**  
**(Sitting as a Judge of the Patents Court)**

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Between :-

(1) BAYER INTELLECTUAL PROPERTY  
GmbH

(2) BAYER AG

(3) BAYER PLC

- and -

(1) ASPIRE PHARMA LIMITED

(2) TEVA PHARMACEUTICAL INDUSTRIES  
LIMITED

(3) TEVA UK LIMITED

(4) STADA ARZNEIMITTEL AG

(5) THORNTON & ROSS LIMITED

(6) GENUS PHARMACEUTICALS LIMITED

(7) SANDOZ AG

(8) SANDOZ LIMITED

(9) ACCORD HEALTHCARE LIMITED

(10) AMAROX LIMITED

(11) HETERO LABS LIMITED

**Applicants**

**Respondents**

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**Thomas Hinchliffe KC and Miles Copeland (instructed by Allen & Overy LLP) for the**  
**Applicants**

**James Abrahams KC and Tom Alkin** (instructed by **Taylor Wessing LLP**) for the **First Respondent**

**Justin Turner KC and Jennifer Dixon** (instructed by **Bristows LLP**) for the **Second and Third Respondents**

**Guy Burkill KC and Tim Austen** (instructed by **Pinsent Masons LLP**) for the **Fourth to Sixth Respondents**

**Daniel Alexander KC and James Whyte** (instructed by **Pinsent Masons LLP**) for the **Seventh and Eighth Respondents**

**Henry Ward** (instructed by **HGF Law LLP**) for the **Tenth and Eleventh Respondents**

Hearing date: 25 March 2024

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## **Approved Judgment**

This judgment was handed down remotely at 2pm on 27 March 2024 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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HIS HONOUR JUDGE HACON

## **Judge Hacon :**

### **Introduction**

1. The principal application before the court is brought by the First Applicant, seeking an interim injunction. During the hearing I gave permission for the Second and Third Applicants to be joined as co-applicants. I will refer to all the applicants individually and collectively as “Bayer”. Bayer seek to restrain the sale by the respondents of a pharmaceutical having the generic name rivaroxaban when sold for once-daily administration. The product was the subject of a trial heard by me concluding on 22 February 2024. The injunction sought is until the order to be made consequential upon the handing down of my judgment.
2. Bayer own a patent which protects rivaroxaban as a compound. That patent as extended by an SPC will expire on 1 April this year. Up to now Bayer has had the rivaroxaban market to itself, selling the product under its brand name Xarelto.
3. In a week’s time others will be entitled to market rivaroxaban with the important qualification that Bayer is also the owner of European Patent (UK) No. 1 845 961 (“EP 961”). EP 961 has Swiss-form claims which, in broad terms, cover the use of rivaroxaban for the manufacture of tablets for once-daily oral administration to a human patient. It expires in January 2026.
4. The respondents to the application are all companies that wish to sell generic rivaroxaban. They have mostly indicated their intent to start sales after 1 April, including sales of tablets for once-daily administration.
5. At the trial I heard six joined claims for revocation of EP 961 which were brought by most of the respondents before the court today. There was a counterclaim for infringement by Bayer, plus a claim of infringement against four third parties. Infringement was not disputed, at least for the purposes of the proceedings. The trial was solely about the validity of EP 961, turning on inventive step and other grounds.
6. I told the parties at the hearing that judgment will be handed down in the first week of next term, probably on 9 April 2024, a little under 7 weeks from the end of the trial. Argument on the form of the order will be heard on 11 or 12 April 2024. There will therefore be a window of 9-10 days after the compound patent expires before there is a possibility of a permanent injunction against the respondents restraining sales of once-daily rivaroxaban in the event that EP 961 is held valid. The purpose of Bayer’s application is to keep the window shut.
7. Come what may, from 2 April 2024 the respondents will be able to sell rivaroxaban in forms suitable for administration twice or more daily, if they wish.
8. Representation of the parties was as shown at the head of the judgment. The ninth respondent was not represented and did not appear.

### **Aspire Pharma**

9. The second to eleventh respondents were all parties at the trial and are liable to be enjoined by a permanent injunction if EP 961 is held valid.

10. The first respondent, Aspire Pharma Limited, was not a party to the trial. On 7 February 2024 Aspire brought a claim against Bayer for a declaration for non-infringement of EP 961, raising a point of construction that was not in issue at the trial. Aspire seeks a listing of the trial in July. At the present hearing I gave directions dealing with the listing. In the meantime Aspire consents to an interim injunction. Aspire says that if another generic company launches a generic rivaroxaban product while the interim injunction is in force, that will constitute a material change of circumstances so that Aspire will be entitled to lift the injunction. Bayer dispute this but argument on the point will be dealt with if and when it arises.

### **Other applications**

11. There were three other applications. One was by Bayer for permission to amend its Part 20 Counterclaim to add Bayer AG and Bayer plc as additional Part 20 Claimants. The reason for the application was to include Bayer companies which are said to suffer potential harm if the interim injunction is not granted. This was resisted only by the fourth, fifth and sixth respondents (collectively “STADA”) which argued that it was not clear from the documents so far provided by Bayer that any damage suffered were there to be no interim injunction would fall on the proposed new applicants. The point was also made that liability for damage appeared to depend, in part, on a licence recently made exclusive and which is terminable by Bayer AG at any time.
12. It seemed to me that these are all points that can be raised at an inquiry as to damages, should there be one. I gave permission to join the two further Bayer companies as second and third applicants.
13. Secondly there was an application by the second and third respondents (collectively “Teva”) for permission to rely on evidence from Dr Avantika Chowdhury in the application for an interim injunction. Dr Chowdhury is a professional economist who gives evidence about the uncertainties or otherwise which are liable to surround an assessment of damages – to Bayer if there is no interim injunction and to Teva if there is one. Admission of this evidence was resisted by Bayer on the ground that it was served less than 2 working days before hearing. Bayer and the respondents took me through their respective accounts of the history of exchanges leading to the hearing of the interim injunction and why, in each case, the opposing side was culpable of delay. I have not sought to work through the detail of the correspondence and sequence of events. Service of Dr Chowdhury’s evidence was not as timely as it should have been but I have the impression that there has been a degree of delay on each side. Bayer had two working days and a weekend to digest and work out their response to Dr Chowdhury’s report. I took the view that it would be just to have its contents debated and gave permission for Teva to rely on the report. Leading counsel for Bayer seemed well able to deal with it at the hearing.
14. Thirdly, STADA filed an application notice on the day of the hearing seeking permission to rely on expert evidence from another economist, Richard Williams. I did not give permission, partly because the application was so late and partly because, having looked through the report in court (it had not reached me before then), it seemed to me that the report mostly or possibly entirely consisted of argument which Stada’s leading counsel could advance in any event. He did.

### **Communication with the court**

15. In October 2021 the Technical Board of Appeal of the European Patent Office allowed an appeal from the Opposition Division and upheld the validity of EP 961. From that time all the companies with ambitions to market rivaroxaban tablets for once-daily administration knew that they had two and a half years to challenge the validity of EP 961 in any EPC State in which they intended to sell. In this jurisdiction, the first claim form seeking revocation of the patent was filed by the seventh and eighth respondents (“Sandoz”) and the ninth respondent (“Accord”) a full year later in October 2022. Other claim forms followed later still. The claims were joined and so far as I can tell, until the question of a trial date was in view they progressed without unusual haste. A consequence was that the trial was fixed for hearing dates that ended about five and a half weeks before 1 April 2024.
16. On the first day of argument at the trial, counsel for the claimants (the parties seeking to revoke EP 961) said that the claims had been case managed so as to try to ensure that judgment could be handed down before 1 April 2024. To the best of my recollection no more was said about it. I was of course aware of the significance of the date and aimed to meet the proposed deadline, though other commitments also had to be dealt with. What I did not know about was the consequence of overrunning 1 April by 9-10 days. On the working day before the hearing of the present application I was taken aback by the scale of it, particularly the number of counsel and solicitors involved and presumably the huge cost incurred. It may be that the parties’ legal advisors, being steeped in their exchanges from early in the year about a possible application for an interim injunction, assumed that everyone realised the scale of the likely consequence of judgment not being handed down in time for argument on the form of order by 1 April. I did not.
17. The point is that in circumstances such as this parties should keep the court informed. It may or may not be possible for a preferred deadline for the handing down of a judgment to be met, this is always a matter of giving priority to commitments. But if the court is properly informed, such as by a jointly agreed brief summary of reasons and possible consequences filed at the trial or subsequently, the court will be in a better position to give the matter appropriate priority. The parties may for their part be given an update of the likely date of the judgment, which in the present case may have affected their willingness to spend large sums on the application. In short, better communication with the court is desirable.

### **The law**

18. The principles to be applied by the court in an application for an interim injunction remain those explained by Lord Diplock in *American Cyanamid Co v Ethicon Ltd* [1975] AC 396. The court must consider:
  - (1) Whether there is a serious issue to be tried.
  - (2) Whether damages would be an adequate remedy to the applicant for the interim injunction in the event that no interim injunction is granted and the judgment at trial finds that the applicant is entitled to an injunction. If yes and the defendant would be in a financial position to pay, no interim injunction will be granted.

- (3) If not, whether damages would be an adequate remedy to the respondent in the event that an interim injunction is granted and the judgment at trial finds that the applicant is not entitled to an injunction. If yes and the applicant would be in a financial position to pay, the interim injunction will be granted.
  - (4) If damages would not be an adequate remedy to either side, where the balance of convenience lies, in particular the balance of likely irreparable harm to each side.
  - (5) If the balance is equal, it is a counsel of prudence to preserve the status quo.
19. *American Cyanamid* was considered and explained by Lord Hoffmann, giving the advice of the Privy Council in *National Commercial Bank Jamaica Ltd v Olint Corp Ltd* [2009] UKPC 16, though nothing arises from that discussion which has a bearing on this application.
  20. Every application for an interim injunction will turn on its own facts. However, there have been judgments on facts having some overlap with those of this application that provide guidance as to the correct approach.
  21. In *Neurim Pharmaceuticals (1991) Limited v Generics (UK) Limited* [2002] EWCA Civ 370 there had been a finding at first instance that the patent in suit was valid and infringed. There was an expedited appeal by the defendants (“Mylan”), associated generic pharmaceutical companies, against the order for an injunction restraining them from infringing the patent in suit. Mylan sought a stay of the injunction pending the outcome of the appeal. Arnold LJ referred to the judgment of Floyd LJ in *Novartis AG v Hospira UK Ltd* [2013] EWCA Civ 583, in which Floyd LJ said that the object is to arrange matters such that when the appeal comes to be heard, the appellate court is able to do justice between the parties and in the meantime an interim remedy that affords the highest available measure of fairness between the parties.
  22. As Arnold LJ went on to explain, this involves an assessment of whether damages would be an adequate remedy in either direction and if not, the balance of likely irreparable harm. Although *Neurim Pharmaceuticals* concerned an application for a stay of an injunction against a generic manufacturer pending appeal, the principles applied were analogous with those of this application.
  23. However, the facts in *Neurim Pharmaceuticals* differed from those of the present application in two important respects. First, Mylan were already on the market, there having been an earlier refusal to grant the claimants an interim injunction pending trial. Secondly, Arnold LJ found that on the evidence Mylan would be the only generic supplier on the market pending the outcome of the appeal. He distinguished this circumstance from that in which there is more than one generic supplier:

“[30] ... The status quo is that there is only one generic supplier in the market place. In that situation it is generally not in the interests of the generic supplier to engage in a price war (as opposed to undercutting the patentee by a certain percentage), and there is no suggestion that Mylan have done so. By contrast, the presence of two or more generic suppliers commonly leads to a price war between the suppliers, and hence a downward spiral in the price which is apt to

cause the patentee damage which is difficult to quantify even if the patent monopoly is subsequently restored by an injunction.”

24. Arnold LJ also considered the likely damage to Mylan if there was no stay of the injunction and Mylan were to be successful on appeal:

“[32] ... Mylan contend that they would suffer unquantifiable damage during the period after expiry of EP443 for three reasons: (i) loss of their current first mover advantage at the point of market entry by other generic suppliers upon expiry of EP443; (ii) the adverse effect on Mylan's contracts with two regions of NHS England and with NHS Wales for the supply of Circadin and other products and on Mylan's ability to tender successfully for future NHS tenders; and (iii) the adverse effect on Mylan's relationships with customers and market credibility if forced to withdraw its product for two-three months.

[33] In my judgment Mylan's damage would be difficult to quantify and adequately compensate for at least the first of these reasons. As the sole incumbent generic supplier, Mylan have an advantage upon expiry of [the patent in suit] because they will have a right of first refusal of future contracts to supply pharmacies. Not only would they lose that advantage if a stay were refused, but also they would be faced with trying to re-establish their foothold in the market after having been forcibly removed from it. In my view it would be very difficult to quantify the extent of the resulting loss of sales compared to the counterfactual in which no injunction had been granted. In addition, I consider that the damage to Mylan would be likely to be more difficult to quantify and adequately compensate than the damage to [the claimants].

[34] Furthermore, even if I were of the view that both sides were equally likely to suffer damage that could not be adequately compensated, it would be prudent to preserve the status quo pending the appeal.”

25. Birss LJ agreed, but put extra emphasis on this last point about the status quo (Neurim/Flynn are the patentee claimants):

“[37] I agree with all the conclusions reached by Lord Justice Arnold but there is one aspect of the matter of the stay in which I would put the emphasis slightly differently. I agree about the principles to be applied, I agree that a stay should be granted, and I agree the condition sought should not be imposed. I would hold that there is a material risk that damages will be an inadequate remedy for each party in the relevant circumstances (for Mylan if no stay is granted but Mylan win the appeal, and for Neurim/Flynn if a stay is granted and Mylan lose the appeal). This is clearly so for Mylan but I believe it is also true for Neurim/Flynn. If Neurim/Flynn win the appeal then there will be a damages enquiry relating to Mylan's patent infringement. The various features of this market and the complexities, actual and potential, are all matters which the Patents Court is familiar with and can handle. The court is well able to conduct a damages enquiry in the circumstances of this market and to arrive at a figure it finds to be just. However that does not mean that damages are an adequate remedy. The uncertainties in this case, relevant to either side, are very significant. In mathematical terms a numerical result can always be found but the error bars will be large. In my judgment the decisive factor here, given that

the appeal has been expedited and will be resolved before the patent expires, is the preservation of the status quo. That status quo is that Mylan is on the market and has been since September 2020. The uncertainties do not justify disturbing that state of affairs.”

26. Newey LJ agreed with both judgments, adding that like Birss LJ, he considered that perhaps the most important factor was that preservation of the status quo favoured the grant of a stay.

27. The points which emerge from the judgments are that while each case turns on its facts:

(1) Where there are or will be two or more manufacturers competing for the generic market, this commonly leads to a price war between the suppliers and hence a downward spiral in the price which is apt to cause the patentee damage which is difficult to quantify even if the patent monopoly is subsequently restored by an injunction.

(2) Where the defendant is the only player in the generic market, there is no incentive for it to reduce its price much below that of the branded manufacturer. Moreover, being the first generic supplier is likely to carry a particular advantage by way of accumulating loyalty to its own supplier brand that would be lost if kept off the market in the relevant period by an injunction.

(3) If one or more generic suppliers are already on the market, irreparable damage to them may be caused by an injunction restraining their sales, being those identified by Arnold LJ in his paragraph [33].

(4) Where both sides are equally likely to suffer damage that could not be adequately compensated, specifically where the uncertainties involved in a future calculation of damages on each side are of a similar order, preservation of the status quo assumes importance.

28. Points (1) and (4) apply to this application, the other two do not. I was referred to earlier judgments in which one or more of the same factors were applied in reaching a decision. I need refer only to one, in which Arnold J as he then was expanded on the potential damage to a patentee where generic competition drives down the price of the drug in *Teva Pharmaceutical Industries Limited v Actavis UK Limited* [2015] EWHC 2604 (Pat), being the permanent effect of the price depression:

“[32] ... Certainly, there is no evidence of any instance where a pharmaceutical company which has sought an interim injunction in circumstances such as these has been successful in raising its prices after refusal of the interim injunction but success at trial.

[33] In addition, one must also take into account such questions as the uncertainty as to the extent of the price depression, how long it would last beyond trial, and what other factors might impact on it, such as alternatives to the infringing product becoming available.”

29. In some earlier cases, a factor taken into account was whether the defendant had “cleared the way” before launching its product. In *SmithKline Beecham plc v Apotex*



*Europe Ltd* [2003] EWCA Civ 137 the court found that the irreparable harm was evenly balanced and that the two factors which carried weight were the maintenance of the status quo and the fact that the defendant had not cleared the way (Apotex was the defendant generic supplier, SB the claimant patentee):

“[39] ... It was Apotex who knew the process that was to be used and when they intended to launch their product, but they refrained from telling SB until the late autumn of 2002. If they had wanted to they could have had the issue of infringement and validity decided before launch. They chose not to do so with the result that there was potential injustice whichever way the court decides.”

30. Although submissions on clearing the way were raised in argument in this application, in my view no issue against the respondents arises under this head. They did not sit on their hands, but brought claims seeking to revoke EP 961.

### **The relevant period**

31. The period of the injunction sought by Bayer in its application notice is until the order following judgment – as I have said a period of 9-10 days after the date on which Bayer’s SPC for the compound rivaroxaban expires.
32. Bayer argued that this notwithstanding, the relevant period should be deemed to be much longer. Bayer submitted that there is sure to be an appeal whatever the outcome of the trial: if the defendants succeed, Bayer will appeal and seek an interim injunction pending the outcome of their appeal; if Bayer wins, the defendants will surely seek a stay of the injunction pending the judgment on appeal. The issues will be much the same save for the short relevant period of this application. The present application should therefore be treated as resolving the position until judgment on appeal.
33. I disagree. The application notice concerns an interim injunction for 9-10 days, nothing more. I do not doubt that the parties will wish to field further evidence and argument should there be an application for an interim injunction or a stay of the permanent injunction pending appeal as Bayer predicts. Bayer said that they wanted the chance to respond to Dr Chowdhury’s evidence. It is possible that new considerations will arise aside from the period under review here.
34. The main point is that I am concerned only with the application currently before the court, subject to one qualification. The importance to be attached to the maintenance of the status quo in an interim application of this type between a patentee pharmaceutical company and a generic manufacturer gives relevance to the possibility of a future application pending appeal. Treating the whole period from 2 April 2024 until judgment in the appeal as one single period would mean that status quo relevant to that entire period is the status quo now: Bayer has a monopoly of the market. If there is no interim injunction for the 9-10 days, the status quo will have changed by the time of a hearing to resolve the interim position pending appeal. The outcome of that later hearing would be significantly affected by what is before the court now regarding just the 9-10 days. It would also have the potential to create the odd result that the rivaroxaban market is opened to generic manufacturers for 9-10 days and then closed until the appeal or January 2026. To that extent, the likelihood of an appeal and the further hearing contemplated is to be borne in mind.

35. STADA argued that the status quo depends on the patents in force at the relevant time; the status quo is going to change anyway on 2 April 2024 because Bayer's patent protecting rivaroxaban as such will have expired. I disagree. In my view the status quo which the Court of Appeal had in mind in *Neurim Pharmaceuticals* was that of the reality on the ground – which products are on the market and which not.

### **Background facts**

36. The market for rivaroxaban is large and correspondingly lucrative for those who supply the drug.
37. Rivaroxaban is overwhelmingly supplied in the course of primary care, that is to say by pharmacies to patients. All such supply is in response to a prescription by a GP. A very small proportion of the supply takes place in hospitals.
38. Almost all prescriptions for rivaroxaban are written generically, which means that when generic rivaroxaban becomes available it will be open to pharmacies to supply the drug in generic form. The vast majority of prescriptions are for tablets indicated for once-daily dosing.
39. In this country pharmacies which dispense rivaroxaban to patients against a prescription are reimbursed by the NHS according to a fixed tariff which differs according to the nature of the product supplied and the content of rivaroxaban in each dose. Drugs available only in branded form are allotted a different category (category C) in the NHS tariff to those also available in generic form. When a drug becomes available in generic form, it is moved from category C to another category (A or M, the distinction does not matter here). The NHS tariff for a drug in generic form is lower, probably very much lower than the branded price. An example given in the evidence relates to an antithrombotic drug called apixaban. Its price when sold under the branded name Eliquis is £53.20; the tariff price for the generic is £4.97. It was agreed, however, that the 9-10 days starting on 2 April 2024 is too short a period for an NHS decision to change the category of once-daily rivaroxaban even if supplies of generics become available during that time.
40. Rivaroxaban is one of several direct oral anticoagulants, or DOACs, available for prescription. The alternatives include apixaban which became available in generic form in April 2022. The evidence included a graph showing sales of branded and generic apixaban between February 2019 and December 2023. The relevant exhibit is marked confidential but unsurprisingly it shows that from April 2022 there has been a dramatic increase from zero in generic sales and a corresponding dramatic decline in sales of branded Eliquis.
41. The National Institute for Health and Care Excellence (NICE) issues guidance which recommends four DOACs as options: apixaban, dabigatran, edoxaban and rivaroxaban. In January 2022 the NHS published an operational note making recommendations to clinicians as between the four. Sales of drugs made available by the NHS are influenced by guidance issued by the NHS which ranks competing products by value. Guidance was issued in January 2022 for DOACs in the treatment of atrial fibrillation (AF). At that time all four alternatives were protected by patents. The document stated that for patients commencing treatment for AF, subject to NICE appraisal clinicians should use edoxaban where clinically appropriate. If edoxaban is contraindicated or not clinically

appropriate, the recommendation was to consider rivaroxaban first, then apixaban and finally dabigatran. After apixaban had become available in generic form, the guidance changed in January 2024 to recommending, in order, generic apixaban, branded edoxaban, branded rivaroxaban, branded dabigatran and finally branded apixaban.

42. In both January 2022 and January 2024 clinicians were given greater leeway in respect of patients already prescribed a DOAC. In such cases commissioners may wish to develop a local policy.
43. Bayer argued that the combination of apixaban becoming generic and changing NHS guidelines made the overall market for rivaroxaban highly uncertain. That may be, although the figures for monthly prescriptions of rivaroxaban between December 2013 and December 2023 suggested that following a growth up to around December 2019, prescriptions have been fairly steady.

### **The issue**

44. As might be expected, the parties agreed that there is a serious question to be tried. It has been tried and judgment will be given in the first week of next term. There was no dispute that there is a potential for irreparable harm to one side or the other whether an interim injunction is granted or not. The issue between the parties concerned the balance of irreparable harm.

### **The arguments**

45. Bayer's arguments tended to assume that the relevant period under consideration was that between now and resolution of the inevitable appeal. As I have explained, I do not agree.
46. First, Bayer argued that the entry of many suppliers of generic rivaroxaban is bound to cause a price spiral downwards with long term effects likely to persist after Bayer regains its monopoly position, but which will be difficult to assess. Bayer's evidence was that the fall in price will happen within weeks or months of a generic launch. Bayer developed this by saying that it may be forced to lower its own prices in order to maintain market share. Also, reduced market share would lead to the dismissal of staff and the loss of established relationships and goodwill with partners in the field.
47. Teva argued that the views taken by the courts to date as to where the balance of irreparable damage lies – when the court is considering the positions of a patentee and its branded product on the one hand and one or more suppliers of a generic competitor on the other – have been based on a lack of accurate expert evidence from an economist specialised in the relevant field. Enter Dr Chowdhury.
48. Teva submitted that Dr Chowdhury had been able to demonstrate that the market for rivaroxaban is mature and stable, entirely occupied by Bayer's Xarelto product. Current sales volumes and prices would provide an accurate guide to Bayer's counterfactual sales over the relevant period absent competition. Damages in an inquiry based on the generic suppliers having been wrongly permitted to compete could be calculated with reasonable precision whether such competition led to a spiral down in price or not. Loss from long term reductions in price can similarly be assessed by reference to current prices and sales volumes. There is no reason why Bayer would be

forced to reduce its prices but if it did, the same means could be used for calculating a consequential loss.

49. By contrast, there are no existing figures on which to base likely counterfactual sales of generic products if such sales are prevented. As well as difficulties in establishing the overall counterfactual size of the generic market, it would be very difficult to establish how much of it should be accorded to each party who enters into that market.
50. In oral argument another point arose. I was told that 23 entities have been granted a marketing authorisation for rivaroxaban. Bayer's counsel said that if no injunction is granted over the 9-10 days, all or any of the 17 not parties to this application might start sales of once-daily rivaroxaban tablets, exacerbating the damage to Bayer.
51. Teva's counsel embraced the point and said that an injunction, if granted, would not bite on the 17 non-party entities (he put the figure at 18 but the correct number does not matter), submitting that they are liable to start selling anyway. It would be unjust to Teva (and the other parties) to be restrained when rivals are free to sell, it would be inequitable to grant an injunction that distorted competition in this way and in effect the injunction would be pointless.
52. Bayer's counsel responded by saying on instructions that if any non-party holder of a marketing authorisation started sales in the 9-10 day period, within hours Bayer would apply ex parte for an injunction which would certainly be granted.
53. Teva had an answer: an insurmountable objection to the grant of such an ex parte injunction in almost every case was lack of action on Bayer's part. There had been exchanges between solicitors for Bayer and those acting for holders of a marketing authorisation. In almost all cases the holder had declined to offer undertakings and even where that happened Bayer had done nothing about it. Ex parte relief would not be granted because Bayer could have issued a claim form and joined the relevant holder as a party to this application. In effect, ex parte relief would be denied because of delay.
54. Submissions on behalf of the other respondents, so far as matters, overlapped and reinforced those made by Teva.

## **Discussion**

55. The short and crucial point about this application for interim relief is that it concerns only 9-10 days. I doubt that either Bayer or any of the respondents would suffer a great deal of irreparable harm on the alternative hypotheses of an injunction being granted or not. Bayer's counterfactual sales absent an injunction in that short period should be fairly easy to calculate. The level of Bayer's current sales is known. To the extent that actual sales were to fall below that figure, damages would fall due. I do not say that Bayer is not at risk of any irreparable harm at all because there would be uncertainties, but they would be modest. The same applies in mirror-image to any losses the respondents may suffer in the event of an injunction. Dr Chowdhury's concerns, assuming they are valid, would only arise over a longer period than 9-10 days. If there were an injunction over that short period which is thereafter lifted, it seems to me 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. An area under the curve calculation – the area between the lines of notional and actual sales until they

meet at steady state – would be sufficiently accurate to calculate the losses of each respondent with reasonable accuracy. I would add, meaning no disrespect whatever to Dr Chowdhury, that I am wary of placing full reliance on her evidence when Bayer did not have a sufficient opportunity to respond to it with evidence of their own from an economic expert.

56. The Court of Appeal has emphasised the importance of maintaining the status quo in circumstances such as those of this application. It seems to me that it is all the more important where the period in question is so short. And as I have said, it would change the status quo in respect of any application there may be after judgment is handed down. That has the potential to give rise to significant irreparable harm to Bayer.
57. There remains, however, Teva's argument that the market is going to change anyway because there are authorisation holders for a once-daily rivaroxaban product which are not a party to this application and which are therefore in a position to launch such a product within the 9-10 day period. I know nothing about these authorisation holders and have no idea whether there is a practical likelihood of this happening, but it is possible. Were it to happen, I do not doubt that Bayer would seek ex-parte relief as they have said. I do not accept Teva's argument that the court hearing such an application would be bound to reject it on the ground of delay. The facts would be unusual. The court would be given a copy of this judgment and be aware of the potential that allowing the relevant generic suppliers freedom to market their products before the 9-10 day period is concluded would have the potential to frustrate the intent of an injunction granted pursuant to the present application. The court may conclude that the maintenance of the status quo over a very short period would be appropriate. This is an issue which emerged during oral argument and I am not sure that I had the benefit of fully considered arguments, or reference to relevant authority if there is any, from either side. I am not satisfied that it is a matter which I should take into account.
58. In the result, I will grant the injunction over until resolution of the order to be made following the handing down of my judgment in April. I will hear counsel as to the terms of the injunction.