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Case No: HP-2019-000012

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

The Rolls Building
7 Rolls Buildings
Fetter Lane
London EC4A 1NL

Date: 31 July 2019

Before:

MR. DAVID STONE
(Sitting as a Deputy High Court Judge)

- -

B E T W E E N:

COLOPLAST A/S	**Claimant**
(a company formed under the laws of Denmark)	
- and -	
SALTS HEALTHCARE LIMITED	**Defendant**

- -

Mr Andrew Lykiardopoulos QC and **Mr Maxwell Keay** (instructed by Powell Gilbert LLP) for the **Claimant**

Mr Douglas Campbell QC and **Mr Tim Austen** (instructed by Shakespeare Martineau LLP) for the **Defendant**

Hearing date: 3 July 2019

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APPROVED JUDGMENT

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

DAVID STONE (sitting as a Deputy High Court Judge):

1. On 3 July 2019, I dismissed an application by the Defendant, Salts Healthcare Limited (**Salts**) to stay these patent infringement proceedings brought by the Claimant, Coloplast A/S (**Coloplast**), until opposition proceedings are concluded at the European Patent Office (the **EPO**). As there was insufficient time to give my reasons at the hearing, I said I would give full reasons in writing. That is the purpose of this judgment.

Background

2. The background facts were largely uncontested, and can be briefly stated. Coloplast is the proprietor of European Patent No EP (UK) 2 854 723 B1 (the **Patent**) entitled "comfort layer for a collecting bag" and filed on 17 May 2013. The invention is said to relate to the use of a textile layer consisting of fibre filaments, which is attached to the collecting bag material. The collecting bags are ostomy products for human waste.

3. Coloplast claims in these proceedings under the Patents Act 1977 (the **1977 Act**) that the Patent is infringed by Salts' manufacturing and dealing in its Confidence BE range of ostomy bags in the United Kingdom. Salts' Confidence BE range was launched in or around November 2017. Salts denies infringement, and counterclaims for revocation of the Patent on the grounds that it lacks novelty or is obvious over four prior art references and two alleged prior uses, and also on the basis of insufficiency and AgrEvo-type obviousness.

4. The Patent was opposed at the EPO by Hollister Inc (**Hollister**) on 16 April 2018 on the basis of lack of novelty and lack of inventive step. Coloplast provided its response to the Hollister opposition on 14 September 2018, and the Opposition Division of the EPO issued its preliminary opinion on 18 February 2019. It is common ground that the preliminary opinion is not binding on the EPO.

5. Coloplast sent a letter before action to Salts two days after the EPO opposition period expired. After Salts was served with these proceedings on 5 April 2019, it intervened in the EPO opposition proceedings, as it is entitled to do under Article 105 of the European Patent Convention (the **EPC**). Salts relies on further prior art and further public prior uses which are also said to invalidate the Patent.

6. There will be an oral hearing at the EPO Opposition Division on 26 September 2019 at which it is likely that the Opposition Division will announce its decision. A written decision will be provided within 6 months thereafter. It is recognised by both parties that an appeal will follow to the Technical Board of Appeal of the EPO (the **TBA**). The hearing before the TBA is *de novo* – that is, it is not an appeal only on points of law, but rather a rehearing of the opposition. The estimates of when the TBA will reach its decision differed as between the parties.

7. It is common ground that the UK market is "hugely important to both parties". Coloplast is currently the market leader, but says it is facing increasing competition, including from Salts. The market is worth approximately £120 million per annum.

8. Coloplast has offered an undertaking that if these proceedings are not stayed, it will repay any damages awarded by this court if the EPO later revokes the Patent.

Evidence

9. Witness statements were filed on behalf of Coloplast by Mr Peter Damerell (of Coloplast's solicitors) and Ms Caroline Nilsson (Head of Ostomy Care Marketing at Coloplast), and on behalf of Salts by Mr Nicholas Briggs (of Salts' solicitors), Mr Iain Powner (Head of Research, Quality and Regulatory Affairs at Salts) and Mr Tim Ashton (of Salts' patent attorneys). None of the witnesses was cross-examined, and I accept their evidence, subject to some comments I make below in relation to Mr Powner's evidence on irreparable harm, and the evidence of both sides in relation to time estimates of these and the EPO proceedings.

Legal Principles

10. It was common ground that the principles to be applied are those set out by the Court of Appeal in *IPCom GmbH & Co KG v HTC Europe Co Limited and Ors* [2013] EWCA Civ 1496 (Floyd LJ, with whom Patten and Rafferty LJJ agreed). In *IPCom*, the Court of Appeal reviewed the guidance it had previously given in *Glaxo Group Ltd v Genentech Inc* [2008] EWCA Civ 23 in light of the judgment of the Supreme Court in *Virgin Atlantic Airways Ltd v Zodiac Seats UK Ltd* [2013] UKSC 46, in which Lord Neuberger PSC and Lord Sumption JSC had questioned the correctness of the *Glaxo* guidance. In *IPCom*, therefore, the Court of Appeal "recast" the *Glaxo* guidance as follows:

> "In the light of the observations in *Virgin* and the arguments on this appeal I would recast the *Glaxo* guidance as follows:
>
> "1. The discretion, which is very wide indeed, should be exercised to achieve the balance of justice between the parties having regard to all the relevant circumstances of the particular case.
>
> 2. The discretion is of the Patents Court, not of the Court of Appeal. The Court of Appeal would not be justified in interfering with a first instance decision that accords with legal principle and has been reached by taking into account all the relevant, and only the relevant, circumstances.
>
> 3. Although neither the EPC nor the 1977 Act contains express provisions relating to automatic or discretionary stay of proceedings in national courts, they provide the context and condition the exercise of the discretion.
>
> 4. It should thus be remembered that the possibility of concurrent proceedings contesting the validity of a patent granted by the EPO is inherent in the system established by the EPC. It should also be remembered that national courts exercise exclusive jurisdiction on infringement issues.
>
> 5. If there are no other factors, a stay of the national proceedings is the default option. There is no purpose in pursuing two sets of proceedings simply because the Convention allows for it.

6. It is for the party resisting the grant of the stay to show why it should not be granted. Ultimately it is a question of where the balance of justice lies.

7. One important factor affecting the exercise of the discretion is the extent to which refusal of a stay will irrevocably deprive a party of any part of the benefit which the concurrent jurisdiction of the EPO and the national court is intended to confer. Thus, if allowing the national court to proceed might allow the patentee to obtain monetary compensation which is not repayable if the patent is subsequently revoked, this would be a weighty factor in favour of the grant of a stay. It may, however, be possible to mitigate the effect of this factor by the offer of suitable undertakings to repay.

8. The Patents Court judge is entitled to refuse a stay of the national proceedings where the evidence is that some commercial certainty would be achieved at a considerably earlier date in the case of the UK proceedings than in the EPO. It is true that it will not be possible to attain certainty everywhere until the EPO proceedings are finally resolved, but some certainty, sooner rather than later, and somewhere, such as in the UK, rather than nowhere, is, in general, preferable to continuing uncertainty everywhere.

9. It is permissible to take account of the fact that resolution of the national proceedings, whilst not finally resolving everything, may, by deciding some important issues, promote settlement.

10. An important factor affecting the discretion will be the length of time that it will take for the respective proceedings in the national court and in the EPO to reach a conclusion. This is not an independent factor, but needs to be considered in conjunction with the prejudice which any party will suffer from the delay, and lack of certainty, and what the national proceedings can achieve in terms of certainty.

11. The public interest in dispelling the uncertainty surrounding the validity of monopoly rights conferred by the grant of a patent is also a factor to be considered.

12. In weighing the balance it is material to take into account the risk of wasted costs, but this factor will normally be outweighed by commercial factors concerned with early resolution.

13. The hearing of an application for a stay is not to become a mini-trial of the various factors affecting its grant or refusal. The parties' assertions need to be examined critically, but at a relatively high level of generality."

11. For ease, I refer below to the individual paragraphs above by their paragraph number (for example, "guideline 13"), but both parties submitted that there is overlap between the paragraphs, and that it is the total guidance I must apply.

12. Both Mr Douglas Campbell QC (who, with Mr Tim Austen, appeared for Salts) and Mr Andrew Lykiardopoulos QC (who, with Mr Maxwell Keay, appeared for Coloplast) took me to the *IPCom* guidance, albeit in slightly different ways. There are four points of interpretation of the *IPCom* guidance on which I should briefly comment.

13. First, there was some debate over whether the *IPCom* guidance creates a higher or lower hurdle for a stay than did the *Glaxo* guidance. This is a sterile debate. Both parties submitted that I must apply the *IPCom* guidance to the facts of this case, so it does not assist me to speculate whether I would have reached a different conclusion under the *Glaxo* guidance, nor whether a stay is more or less likely following *IPCom* than it was before.

14. Second, Mr Lykiardopoulos took me to various parts of Floyd LJ's judgment to help in explaining the genesis of the recast guidance at paragraph 68 of *IPCom*. Mr Campbell submitted that the guidance in *IPCom* is set out in paragraph 68, and that, therefore, I should pay less attention to earlier aspects of Floyd LJ's reasons. I disagree. Whilst the recast guidance at paragraph 68 provides a useful summary of the test to be applied, there is nothing in Floyd LJ's judgment that suggests that the rest of his reasons ought to be ignored or discounted.

15. Third, whilst Mr Campbell's skeleton argument contained submissions on the invalidity of the Patent (he described the arguments for invalidity as "strong and numerous"), both counsel submitted that the *IPCom* guidance does not require me to assess likely prospects of success before the EPO. I agree. Guideline 13 makes clear that a stay application must not become a "mini-trial", nor is there any reference in the guidance to prospects of success on either infringement or validity.

16. Fourth, there was a suggestion from Mr Campbell that I should add a gloss to the *IPCom* guidance that imports aspects of the test from *American Cyanamid Co (No 1) v Ethicon Ltd* [1975] UKHL 1. Guideline 1 requires the court to exercise its discretion "to achieve the balance of justice between the parties having regard to all the relevant circumstances of the particular case". Mr Campbell described this as similar to the test on an application for an interim injunction, on the basis that if Coloplast succeeds in this action, it will request a final, rather than interlocutory, injunction. However, in the absence of a stay, and on the assumption that these proceedings will conclude before the EPO proceedings, the final injunction issued by this court will be subject to the outcome of the EPO opposition proceedings. If the EPO revokes the Patent, then this court's injunction will lift, but there will be no undertaking as to damages on which Salts can rely to make good the loss it suffered during the pendency of the injunction. Mr Campbell said he drew support for his submission from paragraphs 34 and 44 of the decision of Norris J in *Fontem Holdings 1 BV and Anor v Ten Motives Limited and Anor* [2015] EWHC 2752 (Pat). In my judgment, the *IPCom* guidelines do not on their face or in their effect import aspects of *American Cyanamid*. The case is not referred to by Floyd LJ, or by Norris J in *Fontem Holdings*. Further, *American Cyanamid* is a different test, for different purposes. It requires an assessment of the merits of the case, at least to the level of determining whether there is a serious issue to be tried, which, as set out in the previous paragraph, has no role in the *IPCom* guidance. It may be that the points raised by Mr Campbell are relevant to any assessment of the appropriate remedies if the Patent is found by this court in due course to be valid and infringed. At that point, it may not be appropriate for the court to issue injunctions, depending on the position of the parties. But, in my judgment, *American Cyanamid* has no role to play in the application of the *IPCom* guidelines.

17. Summarising these four issues, it is clear to me that the *IPCom* guidance provides the roadmap I must follow in exercising the court's discretion to grant or withhold a stay in these proceedings. It is not helpful for me to attempt to provide a gloss on that guidance. Rather, as urged by both parties, I must apply the guidance to the particular facts of this case. I add for completeness that, if I am wrong in that, and I should instead have acceded to Mr Campbell's submissions as I have outlined above, I would still have reached the same conclusion in the exercise of the court's discretion and refused a stay.

IPCom Guidance

18. I therefore turn to the *IPCom* guidance, keeping at the forefront of my mind that if there are no other factors, a stay of these proceedings is the default option, and that it is for Coloplast to show why a stay should not be granted. I also keep in mind guideline 13, which requires me to examine critically the parties' assertions, but "at a relatively high level of generality". I am not to conduct a mini-trial of the various factors.

Delay

19. Guideline 10 notes that an "important factor" in the exercise of the court's discretion is "the length of time that it will take for the respective proceedings in the national court and in the EPO to reach a conclusion". Delay is not an independent factor, but needs to be considered in relation to prejudice to any party, and lack of certainty.

20. Each party filed evidence of the likely timings of proceedings in the case of a stay or no stay.

21. As noted above, Mr Ashton provided a witness statement on behalf of Salts. Mr Ashton is a UK Chartered and European Patent Attorney, and has day to day conduct of the EPO opposition proceedings on behalf of Salts. He has 18 years of experience in the patent attorney profession, including dealing with EPO oppositions and proceedings before the TBA. Mr Ashton provided his estimated timescales for the proceedings before the EPO, estimating that the TBA would reach a conclusion in late 2021, but "perhaps" earlier if accelerated proceedings are granted.

22. Mr Damerell gave evidence on behalf of Coloplast. He is Coloplast's solicitor, with conduct of these proceedings. He provided a different estimate, suggesting that the TBA written decision would be delivered between January 2022 and January 2024.

23. Both parties acknowledged that the nature of EPO proceedings means that the TBA may refer the matter back to the Opposition Division – called the "ping-pong effect". Mr Ashton noted that this "only occurs in very specific circumstances" excluding those of this case. Coloplast submitted that this occurs in 12% of EPO cases. Mr Damerell suggested that a further oral hearing before the Opposition Division, followed by an appeal to the TBA, could mean that the EPO does not finally rule on the validity of the Patent until January 2028. I accept that there is some likelihood of remittal in this case, but that it is not a high likelihood.

24. In summary, the parties' estimates for the EPO proceedings ranged from "late 2021" to January 2028.

25. Salts' evidence on the likely timing of these proceedings was that a trial is likely to take place in October to December 2020, with any appeal heard in mid 2022. Mr Campbell

provided a helpful document titled "Timings of Recent Patent Cases". This had been created using published judgments of this court and the Court of Appeal. He deployed it in support of Mr Ashton's estimate.

26. In contrast, Mr Damerell estimated that the trial in these proceedings would likely take place in June or July 2020 so as to meet the Patents Practice Statement, with any appeal heard in late 2021.

27. So the estimates for these proceedings differed, but differed less than for the EPO proceedings.

28. Each party also made submissions on the impact of expedition. Given the time it has taken for Coloplast to progress these proceedings, expedition is unlikely to be granted were it to be sought. The evidence on EPO expedition was mixed, suggesting it may make a small difference, or may make no difference at all because the EPO is currently unable to accommodate requests. Mr Lykiardopoulos quoted from the 2018 Annual Report of the EPO in relation to the backlog of cases, noting "pendency will nevertheless grow in the short term". As far as I can see based on the available evidence, it seems to me with the best will in the world, expedition at the EPO is unlikely to shorten matters significantly.

29. Whilst each party criticised the other's estimates, it is important to recall that litigation is by its nature uncertain, and these estimates are no more than that. There appeared to me to be a tendency to stretch the estimates a little – with Salts shortening the likely timing of the EPO proceedings and elongating the likely timing in this court, and Coloplast suggesting the opposite. Examining critically the parties' assertions as the *IPCom* guidance requires me to do, it appears to me that the likely timings are as follows:

    (a) The EPO will render an oral decision on 26 September 2019, with a written decision provided within 6 months;

    (b) This court will hear these proceedings in or around July 2020, and provide a written judgment within 3 months;

    (c) The TBA is likely to take at least 2 years to render its decision (January 2022) and "ping-pong" is possible but not likely; and

    (d) The Court of Appeal will rule on any appeal in approximately late 2021.

    I also add that, if these proceedings are stayed until the conclusion of the EPO proceedings, it will be some years before these proceedings can be heard – on Salts' best case, in 2022, and on Coloplast's worst case not until after 2028. Mr Campbell suggested that the comparison I make ought not to be the one I have just set out, but rather a simple comparison of which tribunal will reach a decision first. That may be true in relation to some of the possible outcomes – for example, if there is no stay and the TBA and the Court of Appeal both rule that the Patent is invalid. But I am also concerned with the outcome of a situation in which a stay is granted, and the EPO eventually rules that the Patent is not invalid. In that circumstance, Coloplast would then be entitled to pursue these infringement proceedings, by that stage delayed by three years (and perhaps considerably longer).

30. There was also a suggestion that Coloplast's delay in bringing proceedings for 18 months after the launch of Salts' product ought to count against it in the exercise of the court's discretion. However, Mr Campbell acknowledged that delay in bringing proceedings (or,

indeed, delay in requesting a stay) are not stand-alone factors mentioned in *IPCom*, but rather he submitted, sound in the wider issue of whether some commercial certainty would be achieved at a considerably earlier date, within guideline 8. If proceedings are commenced earlier, the national proceedings are likely to be determined earlier, which weighs against a stay. I accept Mr Campbell's point that any delay in bringing proceedings can affect the timing as he suggested, but it does not seem to me to be a standalone disqualifying factor.

Lack of Certainty

31. Given my findings on likely timings, I must also consider the "public interest in dispelling the uncertainty surrounding the validity of monopoly rights conferred by the grant of the [P]atent". Coloplast submitted that, if a stay is granted, no progress can be made on the issue of infringement until the EPO opposition is finally resolved – in the meantime, Coloplast is unable to assert its Patent. Floyd LJ refers to certainty at paragraph 56 of *IPCom*:

> "it must be borne in mind that national proceedings have the potential to deliver some degree of certainty. A defendant who is held not to infringe the claims of a granted patent by the national court knows that will remain so whatever the EPO decides. Claims cannot be broadened in opposition proceedings. Equally, the decision of the national court that the patent is invalid cannot be undone by the EPO. Moreover a rapid decision of a respected national court may promote early settlement of the dispute as a whole, bringing to an end proceedings everywhere."

32. I accept Mr Lykiardopoulos' submission that a level of certainty will be delivered by the judgment in the trial of these proceedings. As Lewison LJ noted in *Fage UK Limited and Anor v Chobani UK Ltd and Anor* [2014] EWCA Civ 5, a trial is not a dress-rehearsal. So the answer of this court will already go some considerable way to producing certainty for the parties, even if there is then permission granted to appeal. Further, as Floyd LJ noted in *IPCom*, only this court can deal with infringement in the United Kingdom – so only this court can give certainty on whether or not the Patent is infringed.

33. I mentioned above that the United Kingdom market for ostomy bags is competitive. Salts' Confidence BE range is a key competitor of Coloplast's. Salts' evidence was that an average of 400 patients per month have ordered the Confidence BE products since launch. Salts added to its range with the launch of a further product in July 2019. Coloplast therefore submits that, if a stay is granted, there will be no certainty in the short term, as it will not be able to assert its Patent in the meantime. This, it says, puts it at a commercial disadvantage.

34. There is also, as Coloplast submitted, a wider public interest in relation to this particular Patent. Salts' evidence, not contested by Coloplast, was that patients requiring ostomy products are very loyal to the product they first use following the operation at which a stoma is fitted. Change in brand or type of ostomy product is therefore said to be significantly disruptive to a patient's post-operative routine, causing unnecessary anxiety and day-to-day difficulty for patients.

35. Salts used these facts to submit that if an injunction is wrongly granted (that is, a stay is refused, this court finds the Patent valid and infringed, and the EPO later revokes the Patent), then it is likely that Salts' customers temporarily denied the Confidence BE products will never return to the Salts products.

36. To the contrary, Coloplast argued that the loyalty of patients to their ostomy product brand is a reason *not* to grant a stay – on the basis that the sooner certainty can be brought to the market, the better. If, in due course, injunctions issue, there will be fewer patients impacted now than in several years' time, when more patients will be using the Confidence BE product.

37. I prefer Coloplast's submissions. In my judgment, given the nature of the Patent, there is a public interest in early certainty on infringement: certainty that only this court can provide. It is preferable to remove any uncertainty as soon as possible, so as to minimise the number of patients impacted if the Patent is in due course found to be valid and infringed. Every month of delay potentially affects an additional 400 patients. There is, in my judgment, a public interest in dispelling the uncertainty.

Prejudice

38. Salts submitted that it will suffer irreparable harm if the stay is refused, these proceedings find the Patent to be valid and infringed, injunctions are issued, and the EPO later revokes the Patent. Mr Campbell put the prejudice on three footings, with injustice caused by (a) an injunction, (b) an adverse finding, and (c) any award of damages and costs.

Injunctions

39. Salts submitted that the irreparable harm it would suffer is that of patients not returning, given the loyalty to the product they are currently using: if forced by injunctions to use a product other than the Confidence BE, even if only temporarily, they would move to another product, likely a Coloplast product, and never move back to the Confidence BE, even if the injunctions were subsequently lifted.

40. Mr Powner also noted that all of Salts' products are manufactured in Birmingham, and so an injunction in the United Kingdom would disrupt production for other non-UK territories, such as Ireland and Norway, and planned territories such as Australia. Thus, Mr Powner stated that an injunction in the United Kingdom would affect approximately 8,000 patients, approximately 5,500 of whom are in the United Kingdom. Mr Powner also suggested that approximately 50 staff would need to be made redundant.

41. In response, Coloplast submitted that any issues created by the potential for any injunction to be lifted can be dealt with at the time the injunction is requested. Coloplast did not deny that it would seek an injunction – but it said that the court can, at that time, consider whether an injunction is appropriate in light of where the EPO proceedings are up to at that time. Thus, Coloplast submitted, Salts has confused the harm caused by refusing a stay with the harm caused by a future injunction.

42. I agree with Coloplast: the "near irreparable" harm said by Mr Powner to be caused will not arise by virtue of any failure to order a stay. This issue was canvassed by Norris J in *Fontem Holdings* at paragraphs 43 to 45. The judge refused a stay, noting that the defendant could apply to stay any injunction once the patent in that case was found valid and infringed. I respectfully agree – the same applies in this case. As Mr Lykiardopoulos conceded, an injunction is not an automatic remedy, and the court will take into account at that stage any prejudice to Salts: see, for example, the comments of Arnold J in *HTC Corporation v Nokia Corporation (No 2)* [2013] EWHC Civ 3778 (Pat) at paragraph 26.

Adverse Finding

43. In addition to the prejudice caused by injunctions being issued and later lifted, Salts also relied on the prejudice caused by an adverse finding (that is, by this court, that the Patent is valid and infringed). Mr Campbell pointed to paragraph 17 of Mr Powner's evidence:

> "If it transpired that [Coloplast's Patent] was later found by the EPO to be invalid, the damage already caused to Salts as a result of any prior, adverse finding by the UK court, would be near irreparable, and in any case very difficult to accurately quantify."

44. Mr Campbell suggested that I should read this statement to mean that, if there is a finding of infringement, "patients are likely to move away from [Salts' products] even if there was no injunction actually granted forcing them to do so, because they would … lose confidence in the continuing availability of the product."

45. Mr Lykiardopoulos suggested an alternative reading of that statement, given that, in his submission, it follows three paragraphs that deal with injunctions, and paragraph 17 itself goes on to talk about injunctions (as does paragraph 18, the final paragraph of Mr Powner's witness statement). Mr Lykiardopoulos submitted that Mr Powner is saying no more than that injunctions would cause near irreparable harm; he was not suggesting such harm would be caused by a mere finding, absent any injunction.

46. As Mr Powner was not cross-examined, he could not be asked what he meant in paragraph 17 of his witness statement, but it seems to me difficult to suggest that a mere finding of infringement, unaccompanied by injunctions, would have the calamitous ramifications suggested by Salts. Salts' uncontested evidence was that stoma patients do not usually choose their own product – rather, it is suggested by a treating professional. Further, the product dispensed in the operating hospital is the one most patients then use forever, unless there is a particular problem with it. Very few patients were said to go looking for an improved or different product. Hence, it seems to me that any adverse finding is both unlikely to come to the attention of patients in the absence of an injunction, and unlikely to have any effect on their ostomy product choice should it happen to do so. To the extent Mr Powner's evidence was suggesting otherwise, it does not, in my judgment, accord with the remainder of his evidence. It may be that an adverse finding (without injunctions) would come to the attention of health professionals, but Salts is able and equipped to counter that though its own announcements should it be necessary to do so.

Damages and Costs

47. Mr Campbell noted that an undertaking has been offered by Coloplast to repay any damages awarded if the Patent is later revoked by the EPO. This is to combat the problem identified in *IPCom* guideline 7. But he noted that the undertaking offered did not extend to costs. I do not consider that this argument helps Salts. Both parties considered that the other is "good for the money". This court's powers in relation to costs are wide-ranging, so it is open to the court to delay the payment of costs pending the outcome of the EPO proceedings, should it wish to do so.

48. In summary, I reject Salts' submissions that it will suffer any of the three types of alleged irreparable harm if I refuse to grant a stay. Again, it seems to me that these are matters for submission on the form of order following any finding of infringement. They are not reasons to refuse a stay.

Amendment

49. Patents are often amended in EPO opposition proceedings in order to try to maintain their validity. Amendments (also called auxiliary requests) can only narrow the claims – they cannot broaden them. The result of refusing a stay in this case is therefore that this court may proceed on the basis of the current claims, in circumstances where those claims may then be narrowed before the EPO. If validity of the Patent is maintained by the EPO on the basis of narrowed claims, this court, it was said, will have assessed infringement on the basis of wider claims.

50. Salts submitted that Coloplast has in all likelihood already formulated a set of amendments, and Mr Campbell suggested that these should have been before the court. However, under the timeline applicable in the EPO, Coloplast does not need to serve its requests until 26 July 2019, which was still some weeks off at the time of the hearing before me. In my judgment, Coloplast is entitled to follow the deadlines relevant to the EPO proceedings, and there can be no point taken against it for failing to provide any auxiliary requests to Salts early.

51. Mr Ashton's evidence was that amendments in this case were very likely, and Mr Lykiardopoulos conceded that amendments arise in "almost all validity proceedings, if not all". This, he said, was something Floyd LJ had already taken into account in recasting the *Glaxo* guidelines in *IPCom*: Floyd LJ specifically refers to the possibility of a patent being maintained in an amended form at paragraph 28 of his judgment. Otherwise, Mr Lykiardopoulos said, if amendments were grounds for a stay, then "a stay would become almost automatic". Further, he submitted that, given the deadline of 26 July 2019 for any proposed amendments to be served, they will be known well in advance of the trial in these proceedings. He therefore downplayed the concern that this court would decide the infringement case on the basis of claims wider than those upheld by the TBA.

52. I accept Salts' evidence on the likelihood of amendments, their possible number, and the then likely effect on the trial in these proceedings. However, in terms of timing, on Salts' own evidence (and as accepted by Coloplast), this court will have before it any amendments served by Coloplast on or before 26 July 2019 as well as the written decision of the Opposition Division, and will be able to take those into account at the trial. It seems to me that it is unlikely in this case that this court will reach a decision on claims significantly broader than those that survive in the EPO. If it does (for example, because further amendments are made before the TBA after this court has ruled at trial), then that can be taken into account in relation to remedies and/or in the Court of Appeal. Further, amendments were clearly something Floyd LJ had in mind in *IPCom* in his discussion of the *Glaxo* guidelines. Whilst amendments are not mentioned in the recast guidelines themselves, they are discussed by the Court of Appeal as an inherent part of the system, as Mr Campbell conceded.

53. I am also mindful of Floyd LJ's comments on costs in relation to amendments at paragraph 29 of *IPCom*:

> "There was a tendency in the submissions of Mr Speck for HTC to regard the fact of amendment by the EPO after an English judgment as throwing away the cost and expenditure of the English trial. It does not. There may be some additional expenditure caused by the amendment in the concurrent proceedings but that is a consequence of the system, and is inherent in it."

Costs

54. Salts argued that the risk of wasted costs favours a stay. Costs will be wasted if this court proceeds to a determination, and, in the meantime, the EPO revokes the Patent. Wasted costs are to be taken into account in the weighing of the balance under *IPCom* guideline 12. However, as guideline 12 goes on to note, "this factor will normally be outweighed by commercial factors concerned with early resolution". In my judgment, that is the case here. Whilst there will be wasted costs in the circumstances set out above, that risk is outweighed by commercial factors, including the importance of early certainty, the fact both parties are good for the costs, and the fact that the potentially wasted costs need to be viewed in the context of a market worth over £120 million per annum. Cost budgets have been filed, so the parties know where they stand. Costs on both sides appear to be generally proportionate, given the market for the products.

Balance of Justice

55. Having discussed the detail of the parties' submissions, I must now stand back and consider the balance of justice overall. I remind myself again of guideline 1, and the need for the court to achieve the balance of justice between the parties. I also remind myself of the context for the exercise of discretion set out in guideline 3. I also take into account guideline 4, which expressly acknowledges that concurrent proceedings before the EPO and this court are "inherent in the system", and I remind myself that only this court has jurisdiction over United Kingdom infringement. I further remind myself that the "default option" (guideline 5) is a stay, if there are no other factors, and that it is for Coloplast to show why a stay should not be granted (guideline 6). I have not conducted a "mini-trial", but have examined the parties' assertions critically at a relatively high level of generality (guideline 13).

56. In my judgment, the default position of a stay is displaced. In this case, Coloplast has demonstrated that there are other factors which displace the default option:

    (a) The refusal of a stay will not irrevocably deprive Salts of a benefit of the concurrent jurisdiction of the EPO and this court – Coloplast has offered to undertake to repay any monetary compensation it receives if the Patent is subsequently revoked (guideline 7);

    (b) There is, in my judgment, some commercial certainty that would be achieved at a considerably earlier date in the case of these proceedings (guideline 8). Whilst the parties may not have absolute certainty (or certainty outside the United Kingdom), until the EPO proceedings are finally resolved, it is preferable to obtain certainty at least in the United Kingdom, one of the largest markets for Coloplast and the largest market for Salts, sooner rather than later;

    (c) I have taken into account that the resolution of these proceedings may, by deciding some important issues (including, for example, infringement), promote settlement (guideline 9);

    (d) I have considered the length of time that it will take for each set of proceedings, and have concluded that these proceedings are likely to be concluded first. Certainly, if these proceedings are stayed and the EPO does not revoke the Patent, there will be a considerable delay which, in my judgment, causes significant prejudice to Coloplast. Rather, as noted above, I consider that early determination of these proceedings will

achieve some certainty for the parties (guideline 10): I do not accept that denying a stay will cause irrevocable harm to Salts;

(e) In this case, there is some public interest in dispelling the uncertainty (guideline 11); and

(f) Whilst there is a risk of wasted costs if no stay is granted and the EPO eventually revokes the Patent, in my judgment, this is outweighed by commercial factors associated with early resolution, as guideline 12 suggests will "normally" be the case.

57. Stepping back, I again ask myself where the balance of justice lies between the parties. In my judgment, for the reasons I have set out, the balance of justice will best be achieved by refusing a stay.

58. Coloplast should now give the undertaking it has offered to repay any damages ordered by this court if the EPO subsequently revokes the Patent.