

ConvaTec fails to find a silver lining in its latest dispute with Smith & Nephew

The High Court decided that Smith & Nephew's DURAFIBER AgTM wound care product does not infringe ConvaTec's patent relating to silverised wound dressings, and refused to grant springboard relief to ConvaTec based on infringing experiments carried out by Smith & Nephew to obtain regulatory approval for their product.

Background

ConvaTec owns EP (UK) patent 1343510 which relates to methods of preparing silverised yet photostable materials useful, for example, in wound dressings such as ConvaTec's AQUACEL[®] Ag. Smith & Nephew sought a declaration of non-infringement for its commercial process for making DURAFIBER AgTM, also a silverised wound dressing. ConvaTec counterclaimed alleging infringement, and in addition sought a springboard injunction based on Smith & Nephew's early development work used to obtain regulatory approval.

This is not the first occasion in which this patent has been the subject of a dispute. In a previous action, Smith & Nephew contested validity of the patent, but it was upheld in amended form by both the High Court in June 2012 and the Court of Appeal in December 2012.

The commercial process

Claim 1 specified a method of preparing a light-stabilised antimicrobial material including a step of soaking the material

in a salt solution to facilitate silverisation. The claim specified that the salt is "present in a concentration between 1% and 25% of the total volume of treatment".

Smith & Nephew's commercial process for producing DURAFIBER AgTM uses 0.77% salt, and ConvaTec contended that this falls within the claimed range of 1% and 25% because the lower limit of 1% should be understood to include anything above 0.5%, which rounds to 1%. However, in considering the skilled person's likely approach to rounding numbers in this particular case, the Judge was neither persuaded by this argument, nor by Smith & Nephew's primary case that 1% constitutes an absolute boundary. Instead, he adopted Smith & Nephew's secondary argument - the "one significant figure" construction, whereby only anything greater or equal to 0.95% is covered, because 1% is expressed to one significant figure and 0.95% is the lowest percentage that rounded to one significant figure gives 1%. The Judge concluded that Smith & Nephew's commercial process to make DURAFIBER AgTM, using 0.77% salt, does not infringe the patent.

The non-commercial process

In 2009/2010, Smith & Nephew performed experiments which it used to obtain "CE mark" approval for its DURAFIBER AgTM product. CE marking certifies that a product meets the essential requirements of all relevant European Medical Device Directives, and is mandatory before medical devices can be sold in the European Economic Area.

ConvaTec contended that those experiments, which used different steps to the commercial process used above, infringed its patent, and provided Smith & Nephew with an unwarranted advantage, or springboard, in marketing DURAFIBER AgTM. This was on the basis that the CE mark covering DURAFIBER AgTM was obtained using this earlier process, but the CE mark was broad enough to cover DURAFIBER AgTM made by the later commercial process (which had been developed subsequently to avoid the claims of the patent). ConvaTec said this fact justified an injunction against the selling of DURAFIBER AgTM until the date Smith & Nephew would

have obtained CE mark approval if it had applied using the later-developed commercial process (and so if it had not infringed the patent).

Unlike in the first question where 0.77% was relatively far removed from the established lower boundary of 0.95%, in this second infringement question the Judge had to consider a salt concentration that was much closer to the lower boundary. As part of this assessment, first it had to be established whether “carryover” fluid should be included in the term “total volume of treatment”. Such “carryover” fluid is the fluid that the material will carry over from a preceding soaking step. Regarded from the skilled person’s point of view, the Judge decided that such “carryover” should be included. After assessing different ways of calculating the actual amount of “carryover”, the Judge concluded that Smith & Nephew’s experiments to obtain CE mark approval for DURAFIBER Ag™ used 0.96%-0.97% salt and thereby infringed the patent.

Springboard injunction

Nevertheless, the Judge did not grant ConvaTec an injunction. After reviewing the case law on springboard relief and its applicability to patent cases, he established five criteria said to be relevant in considering whether springboard relief is appropriate in a patent case:

1. Caution is required before a final injunction is granted restraining an otherwise lawful activity.
2. The nature of any unwarranted advantage relied on should be identified and the precise relationship between the unlawful activity in the past and the later acts which are said to exploit that unwarranted advantage needs to be considered.
3. If an injunction is to be granted it must be in an appropriate form and for a duration which is commensurate with the unwarranted advantage relied on.
4. The court must be particularly careful not to put the claimant in a better position than it would have been in

if there had been no infringement at all, especially if otherwise lawful competitive activity will be restrained.

5. In considering what relief to grant, the availability of other remedies apart from an injunction needs to be taken into account, not only damages but the availability of an account of profits should be considered too.

Two factors that contributed to the Judge’s decision, in particular in light of criterion (2) above, were that the final commercial product that would be included within the scope of the injunction (were it to be granted) does not actually infringe the patent, and that there is only an indirect relationship (the submission of data to a regulatory authority), which is not itself an infringing act, between the infringing acts and the later non-infringing acts.

Importantly, the Judge was not satisfied that Smith & Nephew would necessarily have had to use the infringing process in order to obtain CE mark approval by the date of the trial (November 2013). On the contrary, the Judge concluded that Smith & Nephew could have obtained CE mark approval by October 2013 based on their later, non-infringing process, which was developed in response to ConvaTec’s patent having been upheld in the previous revocation action. Moreover, Smith & Nephew had stayed off the market until this judgment was handed down, which the Judge viewed favourably and considered that in a sense it had thereby already submitted to a “voluntary springboard” remedy. Smith & Nephew could not be said to be exploiting an unwarranted advantage gained from the infringing experiments and so any springboard relief would in fact overcompensate the patentee for any harm that had been caused by the infringement.

Summary

Smith & Nephew’s commercial manufacturing process did not infringe ConvaTec’s patent. Its earlier experiments that had been used to obtain regulatory approval did infringe the patent, but were found not to justify the award of springboard relief to ConvaTec.

Comment

This judgment touches on issues of construction of numerical ranges and the availability of springboard relief in patent cases. The decision highlights that the scope of numerical ranges, and in particular which rules to be adopted when rounding numbers that are close to the limits of a range, is dependent on the facts of the case and on the “natural approach of the skilled person”. We expect that this judgment will be referred to in future patent cases dealing with the question of when springboard relief is appropriate.

As a postscript to this judgment, in parallel on-going proceedings at the European Patent Office, a recent subsequent decision by the Boards of Appeal remitted the case to the Opposition Division to consider further claim requests submitted during opposition proceedings, having found a lack of inventive step in the claims that essentially correspond to those that were being considered by the UK High Court.

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