IN THE HIGH COURT OF JUSTICE
KING'S BENCH DIVISION
ADMINISTRATIVE COURT
[2024] EWHC 709 (Admin)

No. AC-2024-LON-000843

Royal Courts of Justice

Thursday, 21 March 2024

Before:

MRS JUSTICE LANG DBE

B E T W E E N :

THE KING
(on the application of)
RRR MANUFACTURING PTY LIMITED — Claimant

- and -

BRITISH STANDARDS INSTITUTION — Defendant

- and -

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
Interested Party

MR A HEPPINSTALL KC and MISS F FOSTER (instructed by Dentons UK and Middle East LLP) appeared on behalf of the Claimant.

MR T JOHNSTON (instructed by DAC Beachcroft LLP) appeared on behalf of the Defendant.

MR T LEARY (instructed by the Government Legal Department) appeared on behalf of the Interested Party.

J U D G M E N T

MRS JUSTICE LANG:

1 The claimant is an Australian company, part of the RRR Group, that has developed a device called "CellAED" (which I shall refer to as "the device"). It is a handheld smart personal defibrillator.

2 In May 2021, the device was granted CE certification in the European Union. On 24 August 2022, the defendant (BSI) issued the claimant with a certificate that enabled it to be sold in the UK market. The claimant passed a BSI "Continuing Assessment Surveillance Audit" in March 2023. BSI undertakes regular QMS audits and the claimant passed a QMS review in February 2024.

3 In September 2023, BSI initiated a review of the certificate, at the request of the interested party (MHRA), who had conveyed a number of "concerns" raised by an individual who has a commercial interest in the claimant's competitors, called Mr Martin Fagan of the Community Heartbeat Trust (CHT), and the Resuscitation Council UK (RCUK).

4 Following a "technical surveillance review" on 9 January 2024, BSI issued a report purporting to identify two major and three minor non-conformities and asked for corrective action plans from the claimant (CAPs). This was the First Decision which is under challenge in this claim for judicial review.

5 The claimant appealed on the grounds that, *inter alia*, BSI followed an unfair process in reaching the first decision. On 20 February 2024 the appeal was refused, and supplemental reasons were given on 27 February 2024. This was the Second Decision which is under challenge in this claim for judicial review.

6 BSI has now stated that a decision to suspend the claimant's certificate has been made as a result of the First and Second Decisions. A decision-making panel will decide whether to approve that decision, and make it effective, at any time in the fifteen working days from 6 March 2024 without notice to the claimant. This was the Third Decision which is under challenge in this claim for judicial review.

7 Following a pre-action letter, dated 4 March 2024, the claim was filed and issued on 12 March 2024.

8 The BSI is the UK's national standards body and the UK approved body which exercises its powers and acts pursuant to the Medical Devices Regulations 2002 (MDR 2002) and the retained powers under Annex 11 of Council Directive concerning Medical Devices, 93/42/EEC (the MD Directive).

9 The MHRA is an executive agency sponsored by the Department of Health and Social Care, which regulates, *inter alia*, medical devices in the UK. It has investigatory and enforcement powers. It also designates approved bodies, such as the BSI, to assess the compliance of the manufacturers of medical devices.

10 MHRA registered this device on 12 September 2022. On 13 September 2023, it contacted the claimant to inform it of expressions of concern from unidentified stakeholders, to which the claimant responded. These appear to have been the issues raised by Mr Fagan. It has not taken any decision to exercise any of its powers in relation to the device, but reserves its position in regard to any action it might take in future.

11 The claimant has invited the defendant to agree to a stay of these proceedings and take the dispute to arbitration. This court would be likely to agree to a stay, if the parties both wished to go down that route. However, the defendant has declined the invitation. In my view, the defendant is entitled to proceed to defend its judicial review claim and decline arbitration if it wishes to do so. Judicial review is a completely different procedure to arbitration, in its nature and scope. In those circumstances, I consider it is a matter for the parties to decide whether to proceed with arbitration or not.

12 The claimant has made an urgent application for interim relief to prevent BSI from suspending its certificate pending the outcome of its claim, on the ground that suspension of the certificate on the basis of unlawful decisions would cause serious and potentially irreversible harm to RRR Group, both in the UK and in other jurisdictions.

13 On 12 March 2024, Chamberlain J adjourned the application for interim relief to an oral hearing on 21 March 2024 and gave directions for the filing of skeleton arguments and any evidence. He considered that the claimant's grounds of challenge "disclosed a prima facie case that the decision was unlawful, sufficient to call for an answer".

14 The principles governing the grant of interim relief in judicial review proceedings are those contained in *American Cyanamid Co. v Ethicon Limited* [1975] AC 396, modified as appropriate for public law cases. First, the claimant must demonstrate there is a serious question to be tried. In judicial review claims, this involves considering whether there is a real prospect of the claim succeeding at the substantive hearing: see *R (Medical Justice) v Secretary of State for the Home Department* [2010] EWHC 1425 (Admin) per Cranston J at [6]. It is a higher threshold than the arguablity test applied to the grant of permission in judicial review.

15 Secondly, the court should consider whether damages would be an adequate remedy for a party if the interim relief is either granted or refused. Damages will rarely be an adequate remedy in the context of judicial review claims.

16 Thirdly, the court should consider whether the balance of convenience lies in favour of granting or refusing the interlocutory relief that is sought. This involves balancing the harm to the claimant and to any public interest that would be caused if interim relief is not granted and the claim later succeeds, against the harm that would be caused to the defendant, any third party and the public interest if interim relief is granted and the claim subsequently fails.

17 It is well established that the court will have regard to the principle that it is in the public interest that a decision of a public body should be respected unless or until it is set aside. The strength or weakness of the claim is likely to be a significant factor in assessing the balance of convenience.

18 The claimant relies on four grounds of challenge.

Ground 1: Illegality.

The claimant submits that BSI unlawfully and/or incorrectly exercised its surveillance powers in conducting the October review and has decided to unlawfully exercise its suspension power: see paras.72-79 of the statement of facts and grounds (SFG).

Ground 2: Procedural unfairness.

The claimant submits that BSI has acted contrary to the published statutory and non-statutory procedures and guidance, as well as contrary to natural justice, in failing to follow a fair and transparent process in making the decision: see paras.80-87 of the SFG.

Ground 3: Irrationality.

The claimant submits that BSI has acted irrationally in failing to take into account relevant considerations or to exclude irrelevant considerations in reaching the decision: see paras.88-91 of the SFG.

Ground 4: Fettering of discretion.

The claimant submits that BSI has adopted unpublished policies that improperly restrict its discretion under Regulation 47(5) MDR, has wrongly adopted RCUK guidance of the standard against which to assess the device, and has failed to maintain its independence in permitting itself to be directed by the MHRA: see paras.92-93 of the SFG.

19 The defendant concedes, in the light of the observations of Chamberlain J, that the claimant has passed the merits threshold, applying the *American Cyanamid* case, but it submits the claim is not a strong one and it reserves the right to resist permission in due course.

20 I have carefully considered the defendant's evidence and its submissions set out in its skeleton argument and its response to the claimant's criticisms in correspondence. Whilst some of the claimant's points are stronger than others, I am satisfied that the claimant has demonstrated that there is a serious question to be tried. I do not consider that damages would be an adequate alternative remedy for either party. Therefore, I turn to consider where the balance of convenience lies.

21 I accept that the claimant will suffer considerable commercial and reputational harm, both in the UK and in other countries, if its certificate is suspended, even if only up to the date of trial. I accept that other jurisdictions would rapidly become aware of the suspension and would likely commence their own investigations in the light of it. The device is the claimant's only product and so its entire business could be threatened. If, as the claimant submits, this is a life-saving innovative product, it is not in the public interest to put it out of business.

22 If BSI is restrained from suspending the certificate pending trial, it will be deprived of its power to prevent the claimant from operating in the UK. Public health and safety is obviously a paramount concern. However, there is no evidence that the device is a current risk on health and safety grounds. Although Mr Tunbridge refers, in para.8 of his witness statement, to the fundamental and overarching concerns for public safety when using the device, the BSI has not identified direct evidence that the device is unsafe, and it was content to allow the product to continue to be marketed during the implementation of its CAP requirements. The device has previously been certified and approved by BSI and it is certified and approved in other jurisdictions as well. Certification denotes that the requirements of safety and efficacy have been met.

23 If a risk to public health and safety were to be identified, the MHRA has a suite of powers at its disposal to protect the public. It can issue safety notices, compliance notices or suspension notices. It can also give public warnings about devices. In the event that an injunction is granted, it has stated it will keep the matter under careful review. It has been suggested to me in court that the MHRA might be prompted to take enforcement action

simply because the court has granted an injunction. In my view, that would not be a proper basis on which it should exercise its powers.

24 In my judgment, the balance of convenience lies in favour of maintaining the status quo by restraining the BSI from suspending or withdrawing the certificate until the claim has been determined. I will consider the issue of renewal of the certificate in due course.

25 The proceedings should be expedited, which is in everybody's interests (but not at the expense of proper case preparation). It would be contrary to the overriding objective of dealing with this case at proportionate cost and allotting a proportionate amount of court resources to it, if I made an injunction which only lasted until some further interim stage in the proceedings. That is not this court's usual practice and, in my view, it would be likely to result in one or more applications for an extension of the injunction and potentially further oral hearings like today's hearing, which would be a disproportionate use of limited court resources.

26 In his first statement, Mr Tunbridge helpfully alerted the court to the fact that the claimant's existing UKCA certificate is due to expire on 26 May 2024. Renewal is not automatic. It requires a re-certification review which includes reassessment of the relevant device. Mr Tunbridge states in his second witness statement that BSI would not be able to review the certificate at present "in the light of the identified non-conformities which remain unaddressed". Mr Tunbridge said in his first witness statement:

> "I assume that RRR may also intend to seek a mandatory order compelling the BSI to renew the certificate."

27 In my view, it would defeat the object of the court's order if the claimant's certificate was not renewed because of the decisions which are under challenge and before the court had had the opportunity to rule on their lawfulness. Therefore, I am willing to extend the scope of the injunction to require the defendant to maintain certification in place until the determination of this claim. Presumably that could be an extension to the existing certificate but, if not, then a time-limited renewal. I will hear submissions from the defendant on that in due course.

28 This hearing was not listed as a permission hearing and the BSI and MHRA have not yet filed their summary grounds of resistance. Therefore, I cannot consider permission today. However, I can give case management directions and I think it would be helpful for me to do so.

29 Ordinarily, the next stage would be for the defendant and interested party to file its acknowledgement of service and summary grounds, and then for a judge to make a permission decision on the papers. If permission was refused, the claimant would be entitled to renew its application at an oral hearing. That process obviously takes potentially weeks, if not months. The defendant has suggested a rolled up hearing to save time, in which permission is considered at the same time as the substantive hearing. As I understand it, both parties are in favour of that.

CERTIFICATE

Opus 2 International Limited hereby certifies that the above is an accurate and complete record of the Judgment or part thereof.

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This transcript has been approved by the Judge.