JUDICIARY OF ENGLAND AND WALES

21 September 2018

MEDIA SUMMARY

Bayer Plc and Novartis Pharmaceuticals UK Ltd v Various Clinical Commissioning Groups

Re: Avastin

Judge: Mrs Justice Whipple DBE

BACKGROUND:

Bayer Plc ("Bayer") and Novartis Pharmaceuticals UK Ltd ("Novartis") (together, the Claimants) challenged the lawfulness of a policy adopted by twelve Clinical Commissioning Groups ("CCGs") from the North of England (the "Defendants"). [1]

The policy is headed "Treatment for Age-related Macular Degeneration" (commonly referred to as "AMD", a common condition which can lead to blindness). The policy refers to three different drugs for treating patients with the neovascular form of that condition, which is known as "wet AMD". The three medicines named are (1) **Eylea** (whose INN, or international non-proprietary name, is aflibercept) for which Bayer holds a marketing authorisation which is specific to ophthalmic use; (2) **Lucentis** (INN ranibizumab) for which Novartis holds a marketing authorisation which is specific to ophthalmic use; and (3) **Avastin** (INN bevacumizab) for which Roche holds a marketing authorisation for various uses not including ophthalmic use. [1]. When used for ophthalmic treatment, Avastin is usually "compounded" in which case it can be referred to as compounded bevacizumab, or "CB".

The policy stated that Avastin will be offered to certain patients with wet AMD "*as the preferred treatment option*". [2] and [27]-[30].

The Defendants adopted this policy because of the significant difference in price between Avastin and the other two medicines. Avastin costs around £28 per injection; Eylea costs around £816 per injection; Lucentis costs around £551 per injection, although the actual prices will vary depending on a number of factors, including whether any confidential discount on price has been negotiated with the relevant pharmaceutical company. [3]

GROUNDS:

The Claimants challenged the policy on four grounds: (1) that the supply of Avastin to treat wet AMD patients was unlawful under EU law, because Avastin does not have a marketing authorisation for ophthalmic use. Such a marketing authorisation is required by Directive 2001/83/EC (the "Medicines Directive"); (2) that the use of Avastin for ophthalmic purposes fundamentally undermined the objective of the Medicines Directive and breached the duty of sincere cooperation in Article 4(3) of the Treaty of the European Union ("TEU"); (3) that the use of Avastin for ophthalmic purposes undermined patients' rights of access to treatments recommended by NICE (the National Institute for Health and Care Excellence), namely Eylea and Lucentis; and (4) that a Q&A document and a Patient Information Leaflet which accompanied the policy were misleading and inaccurate in material respects. See [5]

JUDGMENT:

Mrs Justice Whipple dismissed the application for judicial review on all grounds. She found the Defendants' policy to be lawful.

REASONS:

The Court set out the extensive background to the Claimants' challenge ([7]-[66]) and the relevant EU and domestic law ([67]-[138]). The Court concluded that the Claimants' challenge pivoted on a handful of issues which were identified at [139] and resolved at [140]-[198]. In summary, the Court decided in relation to those key issues as follows [258]:

i) The European Medicines Agency does not have exclusive competence to determine whether Avastin is clinically effective and safe for ophthalmic use. NICE and the CCGs also have competence in that arena.

ii) Treating clinicians can lawfully choose Avastin for ophthalmic use on grounds of cost.

iii) The Claimants' argument that Avastin is not safe when used for ophthalmic purposes did not arise for determination in the context of this challenge; but in any event and even if it did, NICE has concluded that Avastin so used is safe (this is a reference to the NICE Guideline NG 82 on the diagnosis and management of AMD, published in January 2018). The NICE Guideline settles the safety issue.

iv) Avastin prepared for ophthalmic use is widely available in the UK and elsewhere. There is an established market in it.

v) Based on guidance from the MHRA in 2011, CB is an unlicensed medicine and not an off-label use of a licensed medicine. The distinction between unlicensed and off-label use appears to depend on a judgement as to the extent of any modification [182]. The Court invited the MHRA to review its guidance that CB was an unlicensed medicine in light of a number of factors [186]-[190] which made the current position, reflected in the 2011 guidance, highly unsatisfactory [186].

vi) The relevant test by which the lawfulness of the Policy is to be judged in domestic law is this: is the Policy realistically capable of implementation by the NHS Trusts in a way which does not lead to, permit or encourage unlawful acts?

The Court noted that the crux of the Claimants' case was that the policy was intended to encourage large scale production of compounded bevacizumab for treating wet AMD. The Defendants said that there were four broad ways, or "modes" in which the CB could be sourced by NHS Trusts and argued that each mode was lawful. The "modes" were: (1) Original vial use (which involves drawing a small amount of Avastin directly from the vial for injection directly into the eye; the balance of the drug remaining in the vial being discarded [211]); (2) Compounded "in house" by the hospital's own pharmacy; (3) Compounded by another NHS hospital pharmacy; and (4) Compounded by a commercial entity which stands outside the NHS. See [199].

The Court agreed with the Defendants that each of the modes at least *might* be lawful. The position for modes (1) and (2) was stronger. Mode (4) might be lawful: even if the commercial providers were acting in breach of EU law, the Court was not persuaded that it would necessarily be unlawful for the NHS Trusts to purchase CB from them. Mode (3) was a hybrid, capable, hypothetically, and depending on the facts, of being categorised either as an "in-house" supply within the NHS (mode (2)) or a commercial supply by a third party supplier (mode (4)). [238]

Turning to the Claimants' grounds, the Court concluded that in light of its conclusion that each of the modes provided a means by which the policy might realistically be implemented, ground 1 failed [239]. Ground 2 failed; the Claimants significantly overstated the protection afforded to them by the Medicines Directive [242], and see [240]-[246]. Ground 3 failed because the effect of the policy was not to undermine NICE; the patient could still choose Eylea or Lucentis [249]. Ground 4 also failed: the patient information leaflet was still in draft and not yet published; there was no decision to challenge; and in any event, it was a document which belonged to the NHS Trusts and not the Defendants. The Q and A document was also in draft but in any event the various points of challenge lacked substance, [255]-[256].

The policy was therefore lawful. The Claimants' application was dismissed.

NOTES: **(1) References in square brackets are to paragraphs in the judgment.**
(2) This summary is provided to assist in understanding the Court's decision. It does not form part of the reasons for the decision. The full judgment of the Court is the only authoritative document. The full judgment of the Court and a copy of this media summary are available at www.judiciary.uk