Neutral Citation Number: [2020] EWHC 329 (QB)

Case No: QB-2018-003766

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 21/02/2020

Before :

MRS JUSTICE EADY

- -

Between :

(1) BIOPLUS LIFE SCIENCES PRIVATE LIMITED
(2) ABBA PHARMA LIMITED
(3) BLUE BIO PHARMACEUTICALS LIMITED **Claimants**

- and –

THE SECRETARY OF STATE FOR HEALTH **Defendant**

- -
- -

Mr Tristan Jones of counsel (instructed by **Bishop & Sewell LLP**) for the **Claimants**
Mr Robert Palmer QC and Ms Khatija Hafesji (instructed by **Government Legal Department**) for the **Defendant**

Hearing date: 28 January 2020

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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.

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MRS JUSTICE EADY

MRS JUSTICE EADY DBE:

Introduction and Factual Background

1. This is a claim for *Francovich* damages relating to the application of the Medicinal Products Directive 2001/83/EC ("the Directive"). At this stage, I am solely concerned with the threshold question whether the provisions of EU law upon which the claimants rely - Articles 6(1), 76(1) and/or 111(1) of the Directive – entail the grant of rights to individuals so as to provide the necessary foundation for the claim.

2. These proceedings relate to authorisation requirements imposed by the Directive in respect of medicinal products. The claimants seek *Francovich* damages for losses said to arise from the defendant's failure to comply with obligations imposed by the Directive to take necessary steps to ensure unauthorised medicinal products were not placed on, or distributed within, the UK market or to carry out required inspections in relation to such products.

3. The claimants produce and supply *Dolenio*, a glucosamine-containing product ("GCP") used for the relief of symptoms in mild to moderate osteoarthritis of the knee. *Dolenio* is an authorised medicinal product for the purposes of the Directive. It was initially authorised in Denmark, but in 2009, by application of the mutual recognition procedure under the Directive, it was authorised for the UK market; an authorisation granted by the Medicines and Healthcare Products Regulatory Agency ("MHRA"), which is part of the Department of Health (it has no independent legal personality). The MHRA is the relevant "*competent authority*" for the purposes of the Directive in Great Britain (in Northern Ireland the Department of Health acts through the Medicines Regulatory Group) and is thus responsible for making sure medicinal products are not placed on the British market, or distributed, without a marketing authorisation, and for inspections to ensure compliance with the legal requirements governing medicinal products.

4. By virtue of the authorisation of *Dolenio*, the claimants had to comply with the requirements of the Directive relating to medicinal products, although other materially identical GCPs were also available on the UK market that were not classified as medicinal products by the MHRA and so did not have to comply with those requirements. The claimants sought judicial review of the MHRA's decision not to classify those other GCPs, complaining that this amounted to a contravention of the obligations imposed on the MHRA under the Directive. Although initially unsuccessful (see the Judgment of Supperstone J in *Blue Bio Pharmaceuticals Ltd and anor v Secretary of State for Health* ([2014] EWHC 1679 (Admin)), that claim was ultimately upheld by the Court of Appeal ([2016] EWCA Civ 554), which quashed the decision not to classify such other GCPs as medicinal products and remitted the question whether such products should be subject to authorisation under the Directive for further consideration by the MHRA.

5. On 21 June 2018, the claimants issued the current proceedings, claiming loss and damage said to arise from the failure to comply with obligations imposed by the Directive, as had been identified in the judicial review proceedings.

6. Having reconsidered its decision, in accordance with the direction of the Court of Appeal, on 24 July 2018, the MHRA concluded that it would classify as medicinal

products all GCPs with a recommended daily dose corresponding to a level of base glucosamine of at least 1178 mg; that is the same level as the glucosamine present in a *Dolenio* tablet.

Francovich Damages

7. *Francovich* damages concern state liability for non-compliance with, or breach of, EU law. As is well known, the cause of action takes its name from Cases C-6/90 and C-9/90 *Francovich v Italian Republic* [1991] ECR I-5357. In addressing the failure by the Italian state to implement the provisions of Directive 80/987, on the protection of employees in the event of the insolvency of their employer, the Court of Justice concluded:

> "33 The full effectiveness of Community rules would be impaired and the protection of the rights which they grant would be weakened if individuals were unable to obtain redress when their rights are infringed by a breach of Community law for which a Member State can be held responsible.
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> 34 The possibility of obtaining redress from the Member State is particularly indispensable where, as in this case, the full effectiveness of Community rules is subject to prior action on the part of the State and where, consequently, in the absence of such action, individuals cannot enforce before the national courts the rights conferred upon them by Community law.
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> 35 It follows that the principle whereby a State must be liable for loss and damage caused to individuals as a result of breaches of Community law for which the State can be held responsible is inherent in the system of the Treaty.
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> 36 A further basis for the obligation of Member States to make good such loss and damage is to be found in Article 5 of the Treaty, under which the Member States are required to take all appropriate measures, whether general or particular, to ensure fulfilment of their obligations under Community law. Among these is the obligation to nullify the unlawful consequences of a breach of Community ….
>
> 37 It follows from all the foregoing that it is a principle of Community law that the Member States are obliged to make good loss and damage caused to individuals by breaches of Community law for which they can be held responsible."

8. Going on to consider the conditions required for such a claim, the Court held:

> "38 Although State liability is thus required by Community law, the conditions under which that liability gives rise to a right to reparation depend on the nature of the breach of Community law giving rise to the loss and damage.

> 39 Where, as in this case, a Member State fails to fulfil its obligation under the third paragraph of Article 189 of the Treaty to take all the measures necessary to achieve the result prescribed by a directive, the full effectiveness of that rule of Community law requires that there should be a right to reparation provided that three conditions are fulfilled.
>
> 40 The first of those conditions is that the result prescribed by the directive should entail the grant of rights to individuals. The second condition is that it should be possible to identify the content of those rights on the basis of the provisions of the directive. Finally, the third condition is the existence of a causal link between the breach of the State's obligation and the loss and damage suffered by the injured parties."

9. Subsequently, in Cases C-46/93 and 48/93 *Brasserie du Pêcheur SA v Federal Republic of Germany, R v Secretary of State for Transport, ex parte Factortame (No. 3)* [1996] QB 404, the Court clarified the three-part test for liability for *Francovich* damages, as follows:

> "51. … the rule of law infringed must be intended to confer rights on individuals; the breach must be sufficiently serious, and there must be a direct causal link between the breach of the obligation resting on the state and the damage sustained by the injured parties."

10. The preliminary issue for this hearing concerns the first of those conditions: whether the relevant provisions of the Directive were intended to confer rights on individuals. Although not expressly stated in *Brasserie du Pêcheur SA*, it is apparent that this first condition must encompass the second requirement identified in *Francovich* - that it should be possible to identify the content of the individual rights in issue on the basis of the provisions of the Directive:

> "The failure of the state to transpose into domestic law the right granted to individuals by the directive must cause the loss and damage of which the subject complains. In order to know whether the subject has suffered a relevant loss we must know the content of the right that should have been created in domestic law. We need to know that because the failure of the member state only causes the subject loss if that failure deprives him of the right that he would wish to assert in domestic proceedings. It is that right that must be found in the terms of the directive…."

See per Buxton LJ at paragraph 35 *Poole v HM Treasury* [2007] EWCA Civ 1021, discussed in more detail below.

The Medicinal Products Directive 2001/83/EC

11. The Directive was introduced under the powers contained in what was then the Treaty Establishing the European Community ("TEEC"). Article 14 TEEC provided (relevantly):

> "Article 14
>
> 1. The Community shall adopt measures with the aim of progressively establishing the internal market over a period expiring on 31 December 1992, in accordance with the provisions of this Article and of Articles 15, 26, 47(2), 49, 80, 93 and 95 and without prejudice to the other provisions of this Treaty.
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> 2. The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of this Treaty."

12. The Directive records that it was introduced having particular regard to Article 95 TEEC, which (relevantly) provided:

> "Article 95
>
> 1. By way of derogation from Article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 14. The Council shall, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.
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> […]
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> 3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective."

13. For the claimants, it is said that it can thus be taken that the object of the Directive is the establishment and functioning of the internal market, taking as a base "*a high level of protection*" to safeguard (so far as relevant) health and consumer protection. The claimants submit that those purposes are then reflected in the Recitals to the Directive, in particular, as follows:

"(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.

(3) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.

(4) Trade in medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products (excluding substances or combinations of substances which are foods, animal feeding-stuffs or toilet preparations), and such disparities directly affect the functioning of the internal market.

(5) Such hindrances must accordingly be removed; whereas this entails approximation of the relevant provisions.

(6) In order to reduce the disparities which remain, rules should be laid down on the control of medicinal products and the duties incumbent upon the Member States' competent authorities should be specified with a view to ensuring compliance with legal requirements.

[…]

(12) With the exception of those medicinal products which are subject to the centralized Community authorization procedure … a marketing authorization for a medicinal product granted by a competent authority in one Member State ought to be recognized by the competent authorities of the other Member States unless there are serious grounds for supposing that the authorization of the medicinal product concerned may present a risk to public health. In the event of a disagreement between Member States about the quality, the safety or the efficacy of a medicinal product, a scientific evaluation of the matter should be undertaken according to a Community standard, leading to a single decision on the area of disagreement binding on the Member States concerned. Whereas this decision should be adopted by a rapid procedure ensuring close cooperation between the Commission and the Member States.

[…]

(14) This Directive represents an important step towards achievement of the objective of the free movement of medicinal products. Further measures may abolish any remaining barriers to the free movement of proprietary medicinal products will be necessary in the light of experience gained, …."

14. The Directive relates to medicinal products, which are defined by Article 1(2):

> "(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
>
> (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis."

15. The first limb of this definition is referred to as the "presentational limb", the second as the "functional limb". The present case is concerned with products falling within the functional limb of the definition.

16. Article 2 then lays down the scope of the Directive. At the relevant time, this provided as follows:

> "1. This Directive shall apply to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.
>
> 2. In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply."

17. Under the terms of the Directive, medicinal products may not be placed on the market within any member state unless they have a marketing authorisation; as Article 6(1) states:

> "1. No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive …."

18. The Directive makes detailed provision for the acquisition of marketing authorisations (see Articles 8-12), with the basic procedures governing the grant of a marketing authorisation then being set out (Articles 17-27) and with a "*Mutual Recognition Procedure*" in respect of cases where an application for marketing authorisation is made in more than one Member State (Articles 28-39). The Directive contains other restrictions relating to the manufacture and importation of medicinal products (Articles 40-52) and makes detailed provision as to their labelling and packaging (Articles 54-69). Criteria are then laid down in respect of the classification of medicinal products as subject to medical prescription or otherwise (Articles 70-75).

19. The wholesale distribution of medicinal products is addressed by Articles 76-85. By Article 76(1) it is provided that:

> "1. … Member States shall take all appropriate action to ensure that only medicinal products in respect of which a marketing authorization has been granted in accordance with Community law are distributed on their territory."

20. Advertising of medicinal products is governed by Articles 86-100. The Directive also contains specific requirements regarding the monitoring of medicinal products (see the pharmacovigilance duties laid down at Articles 101-108) and special provision is made for such products derived from human blood and plasma (Articles 109-110).

21. By Articles 111-119, the competent authority in each member state is required to exercise supervision of the regulatory regime thus laid down by the Directive; by Article 111(1) it is provided:

> "1. The competent authority of the Member State concerned shall … ensure that the legal requirements governing medicinal products are complied with, by means of inspections, if necessary unannounced, and, where appropriate, by asking an Official Medicines Control Laboratory or a laboratory designated for that purpose to carry out tests on samples. This cooperation shall consist in sharing information …"

The specific means by which compliance shall be ensured are then set out.

Do Articles 6(1), 76(1) or 111(1) of the Directive Confer Individual Rights?

(1) The Approach – The Parties' Submissions

22. The question I am required to answer is whether the provisions of EU law upon which the claimants rely - Articles 6(1), 76(1) and 111(1) of the Directive – entail the grant of rights to individuals such as to provide the necessary foundation for a claim for *Francovich* damages. The parties are agreed that the test in this regard is one of necessity; see *Poole v HM Treasury* [2007] EWCA Civ 1021, in which Buxton LJ (with whom the other members of the Court agreed) endorsed the approach laid down by Langley J at first instance in that case, namely:

> "20. … whether it was necessary, in order to achieve the objective of the directive, to confer the asserted rights upon the claimant."

23. The claims in *Poole* were brought by insurers on the Lloyd's market (Lloyd's "names"), who sought *Francovich* damages to compensate for losses in their underwriting business; they contended that their losses arose from the government's failure to transpose into domestic law Directive 73/239, on the co-ordination of laws, regulations and administrative provisions relating to the taking up and pursuit of the business of direct insurance other than life assurance. The appeal against Langley J's rejection of the claims was dismissed on the basis that Directive 73/239 did not necessitate the grant of rights to the claimants. In thus applying the test of necessity, Buxton LJ explained that this approach had been demonstrated both in *Francovich* itself (the creation of rights to payments to workers on the insolvency of their

employer being necessary for the effective implementation of the Insolvency Directive) and in Case C-222/02 *Paul and ors v Germany* [2004] ECR I-9425.

24. In *Paul and ors*, the Court of Justice was concerned with harmonising Directives in the banking field, which imposed supervisory obligations on national authorities with regard to credit institutions. The claims were brought by depositors who had suffered losses incurred through defective supervision of a bank, supervision that they contended would have been in place had the banking Directives been properly transposed by the German government. Allowing that the Directives imposed supervisory obligations on national authorities and that their objectives included the protection of depositors, the Court did not accept that it necessarily followed that those Directives conferred rights on depositors in the event that their deposits were lost as a result of defective supervision by those authorities. In specifically addressing the claimants' claim for *Francovich* damages (one of three claims under consideration), the Court held:

> "50. However, it is clear … that Directives 94/19, 77/780, 89/299 and 89/646 do not confer rights on depositors in the event that their deposits are unavailable as a result of defective supervision on the part of the competent national authorities, if the compensation of depositors prescribed by Directive 94/19 is ensured.
>
> 51. Under those conditions, and for the same reasons as those underlying the answers given above, the Directives cannot be regarded as conferring on individuals, in the event that their deposits are unavailable as a result of defective supervision on the part of the competent national authorities, rights capable of giving rise to liability on the part of the state on the basis of Community law.

25. In *Poole*, Buxton LJ considered that the Court of Justice in the case of *Paul and ors* had made clear that:

> "54 … a mere failure in the supervision required by the Directives does not ground a *Francovich* claim. What is necessary is the grant of a *right* to the depositors. That right must be one to be protected against the failure of supervision that has caused their loss …"

26. For the defendant in the current proceedings, it is observed that similar observations were made by the Court of Justice in *Schmitt v TÜV Rheinland LGA Products GmbH* [2017] 3 CMLR 8, as follows:

> "55 … the Court has previously stated that it does not necessarily follow from the fact that a directive imposes surveillance obligations on certain bodies or the fact that one of the objectives of the directive is to protect injured parties that the directive seeks to confer rights on such parties in the event that those bodies fail to fulfil their obligations, and that is the

> case especially if the directive does not contain any express rule granting such rights …"

27. For the claimants, Mr Jones points out that the Court in *Schmitt* was not concerned with a *Francovich* claim and he does not accept that the reasoning in either that case or in *Paul and ors* lays down any general principle as to the conferment of rights in respect of an obligation of surveillance or supervision imposed by a Directive. Accepting that one of the three questions referred to the Court in *Paul and ors* concerned a claim for *Francovich* damages, Mr Jones observes that it is unclear which aspects of the Court's earlier reasoning were the subject of the reference at paragraph 51 and points out that the conclusion at paragraph 50 was stated to be subject to the caveat that the depositors' compensation requirements imposed by Directive 94/19 must be in place. That said, Mr Jones, does not dissent from the general approach laid down in *Poole*, which is binding on me.

28. Accepting that the right claimed must *necessarily* follow from the provision of EU law relied on, Mr Jones submits that this is something to be ascertained by reference to the purpose of that provision; it does not have to be expressly identified as a right under the Directive. Thus, in C-178/94 *Dillenkofer v Germany* [1996] 3 CMLR 469, the Court of Justice held that a requirement imposed in relation to package holiday retailers - to provide evidence of security for refunds and repatriation of customers in the event of insolvency - entailed the grant of rights guaranteeing refunds and repatriation in such circumstances. In *Dillenkofer*, the Court noted that the purpose of the requirement imposed by Article 7 of Directive 90/314 (relating to package travel, package holidays and package tours) was to protect consumers in the event of the insolvency of package travel organisers. As such, the requirement to provide sufficient evidence of security (the obligation imposed) "*would be pointless in the absence of security actually enabling money paid over to be refunded or the consumer to be repatriated, should occasion arise*." (see *Dillenkofer* at paragraph 41).

29. For the defendant, Mr Palmer QC and Ms Hafesji do not dissent from that proposition but observe that, where the right is to be implied (as in *Dillenkofer*), it must be the necessary implication of the specific provision relied on; in *Dillenkofer*, the Court did not simply refer to the general purpose of the Directive but found that the right to guaranteed refunds and repatriation was necessarily implied by Article 7 itself. The need to focus on the specific provision in issue was further emphasised in *Allen v HMT and anor* [2019] EWHC 1010 (Ch), Mann J observing:

> "53 This is not a general question that falls to be addressed in general terms in relation to the whole of the Directive. It is possible that parts of the Directive can be demonstrated as intended to confer rights on the individual and other parts cannot. The question has to be answered by reference to the rights sought to be asserted and the provisions said to give rise to those rights."

30. Accepting the need to address the objective of the particular provisions in issue, Mr Jones submits that, nevertheless, a purposive approach must be adopted and the court should be careful not to apply an unduly restrictive interpretation of "rights" in this context (per Lord Tyre at paragraph 33 *Angus Growers Ltd v Scottish Ministers*

[2016] CSOH 26). The defendant does not disagree with that approach, but observes that in *Angus Growers* the question whether the relevant Directive created individual rights was not in issue; the court was required to determine whether those rights were limited to the producers' association or could extend to the members of that association.

31. In determining necessity, the claimants further submit that it is relevant to have regard to the practical realities: where, as here, it will only be those in the claimants' position (holders of a marketing authorisation) that will seek to enforce the rights claimed, that points to the conferment of an individual right. Although standing for judicial review purposes did not establish an individual right in a *Francovich* sense, it provided an important context in this regard. That point, the claimants argue, being made all the more compelling given the general EU principle of equal treatment. For the defendant, however, it is observed that the claimants had been able to enforce the right claimed – essentially, to require the member state to do that required of it under the Directive - through the judicial review proceedings, but the claimants' standing to claim judicial review did not establish the conferment of a right for *Francovich* purposes: the fact that the claimants had an interest in the proper enforcement of obligations under the Directive did not necessitate the conferment of an individual right.

(2) The Approach – My Conclusions

32. It is possible to discern some broad agreement as to the approach I am to adopt, informed by the following principles derived from the case-law:

(1) The content of the right claimed must be clear (*Francovich*; *Poole*).

(2) The grant of that right to individuals must necessarily follow if the result prescribed by the provision of EU law in issue (its objective) is to be achieved (*Francovich*; *Dillenkofer*; *Poole*).

(3) To ascertain the prescribed result or objective, regard must be had to the purpose of the provision in issue (*Dillenkofer*; *Allen*).

(4) Having identified the prescribed result or objective of the provision relied on, the question then becomes whether the proper implementation of that provision would entail the conferment of rights on individuals as claimed. (*Francovich*; *Brasserie du Pêcheur; Poole*; *Allen*).

(5) In identifying the nature and extent of the right, a purposive approach is to be adopted and the court should avoid an unduly restrictive interpretation of the right (*Angus Growers*).

33. There is a dispute between the parties as the extent to which the Court of Justice has ruled that the conferment of individual rights for *Francovich* purposes will not be entailed by supervisory and surveillance obligations imposed on member states by EU Directives.

34. The Court of Justice has certainly held that supervisory and surveillance obligations will not necessarily confer rights on individuals, even if one of the objectives of the

EU provision in question is the protection of such individuals (*Paul and ors*; *Schmitt*). I acknowledge, however, the point made by Mr Jones in relation to the cases in question: *Schmitt* did not involve a *Francovich* claim and in *Paul and ors*, although the proceedings involved such a claim, the Court's reasoning was primarily addressed to other bases of complaint. That said, in my judgement, the substance of the Court's reasoning in those cases is clear: a mere failure in supervision or surveillance required under a Directive will not suffice to entail the conferment of the individual right that would found a *Francovich* claim. What is necessary is the grant of a right to individuals in the claimants' position to be protected against losses caused by the relevant failure (see paragraph 54 *Poole*, cited at paragraph 25, above); an obligation of supervision imposed on the member state does not entail an individual right to proper regulation.

35. As for the relevance of the claimants' interest, as acknowledged in the judicial review proceedings: as is common ground, that, of itself, would not entail the conferment of a right for *Francovich* purposes; the test for standing in the context of judicial review is plainly different to that applicable in the present proceedings. More generally, as was noted in *Allen* (see paragraph 55), individual citizens may well have an interest in the proper enforcement of obligations imposed on member states under EU Directives – and, indeed, may suffer from a failure to properly enforce those obligations – but that fact alone will not entail the conferment of an individual right such as to found a *Francovich* claim.

(3) The Application of that Approach in this Case – Discussion and Conclusions

36. Applying those principles, it is first necessary to identify the content of the right claimed. As Mr Jones fairly accepted in oral submissions, the claimants' case in this regard has not always been clear. In the Further Particulars provided in December 2019, it was stated that:

> "7 … the promotion of the internal market and trade in medicinal products requires that the Claimants be entitled to place their products on a market which is properly regulated, i.e. a market in respect of which the United Kingdom is properly discharging its duties under Articles 6(1), 76 and 111(1) to exclude medicinal products which do not comply with the Directive.
>
> 8 Accordingly, the obligations imposed by the Directive on the United Kingdom give rise to a corresponding right, intended to protect the individual interests of the persons concerned in the operation of the internal market, of access to a market regulated in accordance with the Directive."

37. In his skeleton argument for this hearing, Mr Jones reiterated the claimants' reliance on Articles 6(1), 76(1) and/or 111(1) of the Directive, contending:

> "3 … Those Articles, in summary, oblige Member States to take steps to ensure that unauthorised Medicinal Products are not placed on the market. The Claimants say that they have a

> 'right', as that word is used in *Francovich* caselaw, to require the Defendant to discharge those duties."

38. In oral submissions, Mr Jones accepted it was not possible for his clients to claim an individual *Francovich* right to a properly regulated market (as the claimants' case might previously have seemed to suggest). He clarified that the right relied on by the claimants was that asserted in the judicial review proceedings, namely the right to have other products materially identical to *Dolenio* treated as medicinal products for the purposes of the Directive.

39. Having regard to the particular Articles relied on, that must mean the claimants assert individual rights as follows:

    (1) That no such materially identical products may be placed on the UK market absent marketing authorisation issued by the MHRA in accordance with the Directive (Article 6(1)).

    (2) That the defendant will take all appropriate action to ensure that only materially identical products in respect of which a marketing authorisation has been granted are distributed in the UK (Article 76(1)).

    (3) That, in respect of materially identical products, the MHRA ensures, by means of repeated inspections, that the legal requirements governing medicinal products are complied with (Article 111(1)).

40. Having thus identified the apparent content of the rights claimed, the question for me is whether the grant of those rights must necessarily follow if the result prescribed by each provision of EU law in issue is to be achieved.

41. For the claimants it is submitted that such rights must necessarily follow:

    (1) It would be in accordance with the objects of the Directive, to promote the internal market and the trade in medicinal products within the EU (and the fact that the Directive might have other purposes would not be fatal in this regard).

    (2) Those objects are supported by twin pillars, namely: (i) if a materially identical product qualifies for a marketing authorisation then there is an entitlement to that authorisation; and (ii) if a materially identical product does not qualify for a marketing authorisation, it cannot be placed or distributed in the UK market.

    (3) Under the Directive, an entitlement to a marketing authorisation necessarily imports a right to place medicinal products on the market and to distribute those products within the UK.

    (4) That right would, however, be partial and incomplete if the holder of the authorisation had no right to enforce the second pillar, that is to ensure that materially identical products without a marketing authorisation were not placed on the market or distributed in the UK and were subjected to required inspection.

    (5) The holder of the marketing authorisation must be the most obvious person to enforce the second pillar.

(6) Although a degree of discretion was permitted in determining whether to grant a marketing authorisation (as the Court of Appeal had allowed in the judicial review proceedings), that did not mean that the obligations relied on were not sufficiently precise to meet the threshold requirement for a *Francovich* claim.

(7) Specifically, the obligation on the defendant was unconditional: the Directive did not permit medicinal products to be placed on the UK market or distributed within the UK without marketing authorisation.

(8) The claimants' case was made all the more compelling by reason of the principle of equal treatment: where products were materially identical, they should be treated in the same way.

42. The defendant does not dispute the claimants' assertion of a right in respect of the first pillar thus identified: subject to meeting the criteria laid down under the Directive, an entitlement to a marketing authorisation could confer rights on individuals in the *Francovich* sense, to place and distribute medicinal products within the UK. By analogy, this was essentially the same as the right recognised in other cases referenced in the claimants' skeleton argument (see: Case C-127/95 *Norbrook Laboratories Limited v Ministry of Agriculture, Fisheries and Food* [1998] 3 CMLR 809; C-470/03 *AGM-COS.MET Srl v Suomen Valtio* [2007] 2 CMLR 41; C-455/06 *Danske Slagterier v Germany* [2009] 3 CMLR 10). The dispute between the parties really arises at step (4) of the claimants' submissions.

43. The claimants contend that the rights that flow from the entitlement to hold a marketing authorisation can only be meaningful if others are equally required to seek such authorisation in order to place materially identical products on the UK market and to distribute such products in the UK: to give effect to the rights afforded under the first pillar, it is necessary to imply rights under the second. Moreover, the claimants argue that it is inevitable that only individuals in their position (marketing authorisation holders) will seek to enforce the second pillar. Again, to achieve the purpose of the Directive and to give effect to the principle of equal treatment, they must be afforded the *Francovich* rights they claim.

44. Having regard to the objects of the Directive and to the particular provisions relied on by the claimants, I cannot agree that the results prescribed entail the conferment of rights to individuals in the claimants' position, as claimed. It seems to me that there is fundamental difficulty with the claimants' argument, in that it assumes a right to be protected against the consequences of a failure to classify products materially identical to *Dolenio* as medicinal products. The claimants contend that this right is entailed by Articles 6(1), 76(1) and 111(1) of the Directive but, in truth, their claim goes no further than establishing their interest in the defendant's compliance with the requirements imposed by those provisions. The claimants were able to challenge the defendant's classification failure through the courts, by means of their right to seek judicial review. In the judicial review proceedings, it was recognised that the claimants had a relevant interest in that regard but that is not the same as saying that that entailed the conferment of a right to protection against any losses occasioned as a result of that failure.

45. The point is made good once one considers the specific provisions relied on. Starting with Articles 6(1) and 76(1), the intended result of these provisions is to prevent unauthorised medicinal products being placed on, or distributed within, the UK market. As the recitals to the Directive make clear, the prescribed object is to reduce disparities within the internal market while ensuring both that public health is safeguarded, and that the development of, and trade in, medicinal products is not hindered. That object is achieved by the performance of the member state's obligations under the Directive; it does not necessitate the conferment of a right on individual suppliers or distributors of authorised medicinal products in the way claimed in the present proceedings. As the defendant acknowledges, Articles 6(1) and 76(1) may entail the conferment of a right to a marketing authorisation in respect of qualifying products (and see, by analogy, Case C-127/95 *Norbrook Laboratories Limited v Ministry of Agriculture, Fisheries and Food* [1998] 3 CMLR 809) but neither necessarily require a further right, to be protected against any consequences resulting from a failure to classify other (materially identical) products as requiring a similar authorisation.

46. As for the right claimed under Article 111(1), it is clear that its purpose is to prescribe how the member state is to ensure compliance with the legal requirements governing medicinal products; it thus imposes supervisory requirements on the competent authority, but these relate to the manufacture of medicinal products – it says nothing about the prior classification of such products. Individuals in the claimants' position may well benefit from the proper enforcement of this obligation (as may individual citizens more generally), but the purpose of the provision does not require that they have any direct right in this regard. In keeping with the general purposes of the Directive, the object of Article 111(1) is clearly to ensure alignment between member states and reduce disparities within the internal market, while safeguarding public health. Achieving the result required by this provision entails the implementation of the required inspection regime by the member state; it does not necessitate the conferment of an enforceable right on individuals such as the claimants.

47. The question whether the objectives of these provisions necessitate the conferment of rights on individuals in the claimants' position can be tested by asking whether that would be the end result of the proper implementation of the provisions in issue. In the present case, the answer is already apparent. In the judicial review proceedings, the Court of Appeal concluded that the defendant had acted in breach of the obligations imposed by the Directive in failing to properly investigate the classification of other GCPs. The defendant's subsequent implementation of those obligations ensured the prescribed results of Articles 6(1), 76(1) and 111(1) were achieved. That may indirectly have given rise to a benefit for the claimants but it did not necessitate the conferment of any rights on them or on any other individuals that might be in a similar position.

48. The claimants object that this deprives them of a means of enforcing the substance of their rights as holders of marketing authorisations under the Directive, who have had to face unequal competition from materially identical products placed on the UK market, or distributed within it, absent authorisation. That, however, seeks to assume a right that is not conferred by the Directive itself; there is no right under the Directive to protection against losses arising from such competition and the achievement of its objects do not require such a right to be conferred. Moreover, to the extent that the

claimants have an interest in the proper enforcement of the defendant's obligations under the Directive, they plainly have the means of ensuring compliance, as they demonstrated in the judicial review proceedings.

49. Ultimately the claimants' complaint is really founded upon the assertion of a right to a properly regulated market – essentially, the right articulated in their Further Particulars of Claim. It is a claim that seeks to infer an individual right from a more general interest in the proper implementation of a supervisory regime; it fails for similar reasons as identified in cases such as *Paul and ors*, *Poole* and *Schmitt*.

50. The claimants have asked that, if I do not accept their arguments at this stage, I consider whether the provisions relied on are properly to be said to be *acte clair* and, if not, to make a reference for a preliminary ruling to the Court of Justice. That, however, does not seem to me to be a necessary step. The prescribed objects of the provisions in issue are clear; there is no need for a preliminary ruling in this case.

Disposal

51. Having regard to the particular provisions relied on, it is clear that the threshold stage for this *Francovich* claim is not established.

52. In the circumstances, the claimants' claim must inevitably fail and, subject to any further representations by the parties, I consider that the appropriate order would be for this claim to be dismissed.