Abuse of Process: Hormone pregnancy test litigation struck out, forty years after original litigation discontinued

Mrs Justice Yip has struck out 102 claims seeking damages for personal injury and loss alleged to have been caused by hormone pregnancy tests administered in the 1950s, 1960s and 1970s. This follows on from legally-aided test case litigation brought by two infant plaintiffs in the 1970s and 1980s which was discontinued in 1982 on the advice of Leading Counsel and with the permission of Mr Justice Bingham. The new claims, which included one of the original test claim plaintiffs, were issued in 2019 and have now been deemed to be an abuse of process and struck out, on the basis that fundamentally they lacked merit and because the Claimants had been unable to present evidence as to how the Claim could viably proceed to trial.

Introduction and Background

1. In the 1950s, hormone pregnancy tests ("**HPTs**") were released to market as a means to confirm whether a woman was pregnant. They were designed to induce menstruation in women who were not pregnant and so to confirm pregnancy if bleeding did not result. Claims were brought by or on behalf of those born with birth defects who alleged damage caused to the developing foetus by HPTs, and by mothers who suffered miscarriage or stillbirth after taking HPTs.

2. In 1978, the Association for Children Damaged by Hormone Pregnancy Tests ("**the Association**") was established, with the aim of seeking justice for those allegedly affected by HPTs. In the late 1970s and early 1980s, the Association, with the backing of the Legal Aid Board, selected two test cases to pursue claims against Schering AG and Schering Chemicals Ltd, the manufacturer and distributor of Primodos, one of the market-leading HPTs. Hundreds of potential claimants stood behind the test cases.

3. Five years of litigation ensued, which included a trip to the Court of Appeal in 1980 to determine whether four additional test cases should join the original two. Following the exchange of expert evidence, the test plaintiffs were forced to accept in 1982 that there was no reasonable prospect of success in establishing a causal association between the HPTs and the birth defects in question.

4. The Court's permission was needed to discontinue as the plaintiffs were both children. Bingham J permitted the plaintiffs to discontinue on terms that no further action on the subject matter of the proceedings should be commenced without permission of the Court:

> "*The effect of that order is not to shut out the Plaintiffs absolutely. It is open to them to apply in the future in the event of a scientific revolution or a marked change in the circumstances. I should, however, make it clear that for leave to be* given *on any future occasion a very strong case indeed would have to be made out by the Plaintiffs to show that it was just for the matter to be re-opened, and the Court would have to be satisfied that no unreasonable prejudice to the Defendants would accrue. I think it very unlikely that leave to the Plaintiffs would be given, but I think that it is in all the circumstances just that the door should be kept open to that very limited extent*" (underlining added).

Scientific developments since 1982

5. Over the last decade, a series of reviews have been undertaken by or on behalf of the regulatory authorities in the UK and Europe. In March 2015, following lobbying by and on behalf of the Association, the MHRA issued a call for evidence relating to oral HPTs. As a consequence, the Committee on Human Medicines, an advisory non-departmental public body sponsored by the DHSC, set up an expert working group to consider the causative link between HPTs and birth defects, comprised of sixteen experts in various fields. The findings, published in November 2017, did not establish such a link.

6. Those findings were subsequently endorsed by further ad hoc Expert Groups which were assembled to consider new scientific papers published in 2017 and 2018. Reviews were also subsequently conducted by the European Medicines Agency's Committee for Medicinal Products for Human Use. All these reviews concluded that the new scientific papers did not add to current knowledge or give rise to any new concerns.

7. In 2018, the Independent Medicines and Medical Devices Safety Review was established, chaired by Baroness Cumberlege. That review considered three different medical products, one of which was HPTs. It did not, however, focus on causation.

The Instant Proceedings

8. New proceedings were issued initiated in 2019, nearly forty years later. Claims were brought against four defendants: Bayer Pharma and Schering Healthcare, both German pharmaceutical companies; Aventis Pharma (also known as Sanofi) in relation to a different HPT, Amenorone Forte; and the Secretary of State for Health and Social Care, in its capacity as regulator.

9. The claims were commenced by SPG Law (later PGMBM, now Pogust Goodhead) on behalf of 170 claimants – one of whom was Mr Hyman, one of the original plaintiffs in the 1980s litigation.

Abuse of process application and subsequent strike out: the group action case law

10. Following extensions of time granted to the Claimants to gather evidence and plead their claim, Generic Particulars were served in December 2020. The Defendants filed Acknowledgements of Service and concurrently applied for strike out and to require Mr Hyman to obtain permission to proceed in accordance with the Order of Bingham J in 1982.

11. The matter first came before Mrs Justice Yip at a contested CMC in April 2021. She directed that the Defendants' arguments, that the claims should not proceed, needed to be addressed. The Judge directed the applications should be listed with a time estimate of four days, stating that if the Claimants did not have evidence to establish causation, the proceedings would be of no value to anyone and very costly to everybody. The Judge stated that it was important that both sides put their best case before the Court and gave directions for service of evidence.

12. Following service of evidence, in December 2021 the Claimants' solicitors applied to come off the record. In the normal way, that application was heard *ex parte* before a different judge. Mr Justice Turner granted PGMBM's application – see citation [2022] EWHC 670 (QB) – following which some claimants discontinued.

13. At that time, 113 Claimant continued as litigants-in-person, seeking funding and representation. They instructed Counsel through the Advocate pro bono representation scheme. Mrs Justice Yip applied active case

management and set a deadline in October 2022 for the Claimants to indicate whether they had secured funding and representation and how they intended to progress the litigation – see citation [2022] EWHC 1832 (QB).

14. No litigation funding was obtained and no solicitors came on the record. The Defendants' strike out applications and Mr Hyman's application for permission to proceed were duly listed for May 2023 before Mrs Justice Yip sitting in the Rolls Building, London.

15. Some Claimants applied to discontinue in the meantime. By the time of the hearing 102 Claimants remained on the claim form, represented by Counsel on a pro bono basis.

16. The Defendants' abuse of process argument alleged an abuse by re-litigation and an abuse by lack of viability, and was premised on three main arguments [108]:

    a. The Claim was an attempt to re-run the previous litigation, for which there has been no material change in the cause on generic causation, fatal to the overall claim;

    b. The present action was an abuse for being speculative and bound to fail, premised on improperly pleaded claims without a real prospect of proving causation;

    c. Due to the coming off the record of the Claimants' solicitors, and failure to obtain alternate representation, the Claim was unviable, in line with abuse of process case law in group action litigation (*AB & others v John Wyeth & Brother Ltd (No. 5)* [1997] PIQR P385 and *Herbert George Snell & others v Robert Young & Co* [2002] EWCA Civ 1644).

The decision of Mrs Justice Yip

17. The Claim, as pleaded in the Generic Particulars of Claim, was conceded by the Claimants to be "*obviously deficient on causation*" [34]. It did not particularise a causal mechanism by which HPTs could be causally linked to the birth defects in question. A subsequently served draft Amended Generic Particulars of Claim, for which permission to amend was never sought, attempted to do this, but lacked the requisite evidence to support the amendments made.

18. The Judge recognised that the abuse of process jurisdiction was one of last resort, and should not be exercised without a "*scrupulous examination*", following which only in a "*clear and obvious*" case would the power to strike out then be used: *Município de Mariana v BHP Group (UK) Ltd* [2022] EWCA Civ 951 [101-106]. Mrs Justice Yip did not decide the matter on the Claimants' conduct of the case alone, but deemed it part and parcel of the weakness of the Claim's merits and the Claimants' continuing lack of representation [111].

19. Central to Mrs Justice Yip's conclusions, however, was her analysis of the Claim's essential viability. To that end the cases of *Wyeth* and *Snell,* mentioned above, were key. *Wyeth* related to group actions brought for benzodiazepine prescriptions in the late 1980s and early 1990s, and *Snell* related to a group of 100 or so farmers in relation to the adverse health effects of sheep dipping. Both claims had strikingly similar fact patterns to the instant one: originally supported by Legal Aid, withdrawn due to a lack of prospects of success, without sufficient plaintiff proposals to bring the claim to trial. Both were struck out as an abuse of process for lack of viability. In those cases, the Court of Appeal deemed it appropriate to consider the overall merits of the case as well as the fact that the claimants

lacked solicitors and funding necessary to bring their claims. Where there were no viable proposals before the Court on how to progress such the claims, lacking apparent merit and lacking resources, they could be struck out.

20. The Court found that the Claimants in this case similarly lacked viable proposals on how effectively to take the matter to trial. The Association which stood behind the Claimants had some £60,000 in the coffers, recognised to be "limited" for a trial of this magnitude, and no "realistic plan" for the Claim to proceed to trial [117(vi) and (vii)]. Art 6 ECHR did not move the dial; the right to trial is not unfettered, Mrs Justice Yip stated, and would not disturb a finding of abuse where a scrupulous examination has been conducted by the Court [118].

21. Necessary and relevant to this finding was the fact that the claims likewise lacked real prospects of success. The expert evidence adduced on behalf of the Claimants did not purport to establish causation; the pleadings were conceded to be insufficient to plead the required causal link; and the Claimants did not show that there had been a material improvement in the chances of establishing generic causation since the original litigation in 1982 [117(ix)].

22. After four days of oral submissions, Mrs Justice Yip [125-127]:

    a. Denied Mr Hyman permission to proceed without leave of the Court, and found that he did not have such permission given the lack of change in the science since 1982;

    b. Struck out the claims of all the Claimants for abuse of process for lacking a viable plan to progress the Claim and for having no real prospect of success;

c. In any case, having carefully considered the material before the Court, the Judge found that the position on causation had not "materially changed in the Claimants' favour" since 1982, and it would be manifestly unfair to the Defendants to have to continue to defend the action.

23. The claims therefore stand struck out for abuse of process.

Conclusions

24. This case offers practitioners a valuable guide on how to approach complex group litigation, and the importance of 1) formulating such claims clearly and precisely at an early stage, and 2) fully contesting claims at an early stage where they are not properly formulated. It provides an illuminating modern example of the strike out jurisprudence for lack of viability previously set out in the Benzodiazepene litigation in the 1990s and the organophosphate litigation in the early 2000s.

25. It also indicates the importance of organising group claims scrupulously, as such deficiencies may well amount to an abuse of process if not remedied.

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