### THE HIGH COURT

[2023] IEHC 329

Record No. 2018/8314P

Between

#### ANNE MARIE RYAN

PLAINTIFF

and

# EDWARD "EDDIE" MICHAEL O'DONNELL, THE GATE LODGE PRIVATE CLINIC, HEALTH SERVICE EXECUTIVE, FINBAR AIDAN O'REILLY. CORK WOMEN'S CLINIC AND BON SECOURS HEALTH SYSTEM COMPANY LIMITED BY GUARANTEE TRADING AS BON SECOURS HEALTH SYSTEM CORK

**DEFENDANTS** 

# THE HIGH COURT

Record No. 2017/10245P

Between

# MARTINA BRENNAN

PLAINTIFF

and

# PAUL HUGHES, HEALTH SERVICE EXECUTIVE, ETHICON PR HOLDINGS UNLIMITED COMPANY AND RICARD HORGAN

DEFENDANTS

#### JUDGMENT of Ms. Justice Niamh Hyland delivered on 16 May 2023

#### Summary

- 1. This judgment concerns two motions to consolidate in two different sets of proceedings, heard together because of the similarity of the issues raised. In short, in both cases the plaintiffs have sought damages for personal injuries in what are described by counsel as hybrid proceedings, i.e. proceedings where there is a claim in respect of both clinical negligence and defective medical products. At present, there are separate proceedings in respect of the clinical negligence claim and the defective products claim. Both the plaintiffs seek to consolidate their proceedings so that all issues in relation to the alleged personal injury can be heard in the same set of proceedings.
- 2. In deciding on whether consolidation should be ordered, Order 49, Rule 6 of the Superior Court Rules requires me to consider whether there are common issues of fact or law, whether separate proceedings might give rise to confusion or even a miscarriage of justice and whether considerations of expense and convenience dictate consolidation.
- 3. Here, where the plaintiffs seeking consolidation claim that they suffered an injury caused <u>both</u> by the alleged deficiencies in the medical devices implanted <u>and</u> the manner in which they were implanted, the resolution of that claim will potentially necessitate a determination of a number of common

questions of both fact and law, including whether the plaintiff was injured, how the injury was incurred, the cause of the injury, interaction between different actors in causing that injury, allocation of liability and assessment of damages. Should the cases remain unconsolidated, those questions would require to be answered on two different occasions by two different courts. To ask a court to determine these questions in the absence of certain of the parties would in my view be to hobble the trial judge in his or her ability to address the case in a complete and fair manner and would give rise to a risk of duplication and possibly conflicting decisions. One set of proceedings will likely result in a saving of judicial time, and that too is a relevant factor.

4. In those circumstances, I am satisfied that the application of the principles identified in *Duffy* strongly suggest consolidation and I have therefore made the Orders sought by the plaintiffs.

# RYAN

- 5. The motion seeks to consolidate two sets of proceedings, the first being proceedings entitled *Ryan v O'Donnell & Ors*, Record No. 2018/8314P ("Ryan 1") and the second being proceedings entitled *Ryan v Ethicon PR Holdings Unlimited Company & Anor*, Record No. 2020/5899P ("Ryan 2").
- 6. The motion was issued in Ryan 1 and the relief sought is an Order consolidating proceedings pursuant to Order 49, Rule 6 of the Superior Court Rules, as well as an Order permitting the plaintiff to issue and file an amended

personal injury summons in respect of the newly joined defendants. The latter part of that relief referring to the joinder of defendants seems somewhat misguided given that this is an application to consolidate and not to join defendants. I will hear counsel on the wording of the appropriate Order.

7. Order 49, Rule 6 provides as follows:

"6. Causes or matters pending in the High Court may be consolidated by order of the Court on the application of any party and whether or not all the parties consent to the order."

The approach a court should follow in considering an application to consolidate under Order 49 Rule 6 was identified by the Supreme Court in the case of *Duffy v News Group Newspapers Ltd.* [1992] 2 IR 369 where McCarthy J. set out the principles to be applied:

"(1) Is there a common question of law or fact of sufficient importance?
(2) Is there a substantial saving of expense or inconvenience?
(3) Is there a likelihood of confusion or miscarriage of justice?"

8. McCarthy J. noted in *Duffy* that, although the wording of Order 49, Rule 6 was very wide, that did not mean that it was to be applied widely or that a heavy burden did not lie upon those who sought to join or consolidate actions. and that it was a matter of discretion for the Court. Here, for the reasons identified below, I am quite satisfied that "heavy burden" has been discharged by the plaintiff.

#### **Proceedings issued by the plaintiff**

- 9. It is necessary to describe the nature of the two Ryan cases. The plaintiff had a pelvic mesh device inserted at Waterford Regional Hospital on 24 September 2012 in ease of urogynaecological complaints she had been experiencing. In Ryan 1, it is pleaded she was a patient of the first, second and third defendants when a device now known to be a Gynecare TVT Laser Tension-Free Support manufactured by Ethicon PR Holdings Unlimited Company was placed in her by the first defendant. This took place in September 2012. It is further pleaded that in and around July 2015 the plaintiff entered into a contract with the fourth, fifth and/or sixth defendants for the purposes of a second procedure to remedy the injury sustained in the previous procedure and during the course of that procedure, a product of unknown derivation was then inserted in her by the fourth defendant. In the Indorsement of Claim in the personal injury summons of 20 September 2018, it is pleaded that at the time of pleading, the device details had not been provided by the second defendant and the plaintiff awaited confirmation of the contracting party in both procedures and the identity of the supplier of the said devices.
- 10. At paragraph 12 of the Indorsement, it is pleaded that in September 2012, the first, second and/or third defendants supplied a medical device to the plaintiff on foot of a contract between the parties that was unfit for use and dangerous, as a result of which the plaintiff was exposed to harm. It is pleaded at

paragraph 19 that the defendants failed to properly inform the plaintiff of the risks involved in the procedure, failed to ensure the plaintiff was aware of and understood the risks involved in the procedure, provided the plaintiff with a defective product within the meaning of the Liability for Defective Products Act 1991, provided the plaintiff with a medical device that was unfit for use, used materials and/or third party products that were unsound and not fit for purpose within the meaning of the Sale of Goods and Supply of Services Act 1980 and provided third party products not of merchantable quality. Similar pleas are made in respect of the device inserted in 2015 against the fourth, fifth and sixth defendants.

11. The parties to the proceedings in Ryan 2 are Ethicon PR Holdings Unlimited Company and Astora Women's Health Ireland Limited. The Indorsement of Claim of 21 August 2020 contends that both defendants were responsible, within the terms of the Liability for Defective Products Act 1991, for two separate medical devices the defects in which caused the plaintiff loss and injury. Additionally, it is contended that the defendants are jointly and severally liable for negligence, breach of common law and statutory duties and trespass to the person. Finally, it is pleaded that the defendants supplied good which, *inter alia*, were of unfit for purpose, of unmerchantable quality, not reasonably durable and, or alternatively, dangerous, including within the meanings of those terms under the Sale of Goods and Supply of Services Acts.

#### Motion to consolidate

- 12. In the affidavit of Ms. Power, solicitor for the plaintiff, sworn 2 November 2022 grounding the consolidation motion, it is pleaded that a defective product claim benefits from a longer statute of limitations than that which applies to a professional negligence claim and that authorisation is required. At the hearing, counsel noted that the situation has changed in this respect following the decision of the Court of Appeal in *Creedon v DePuy* [2021] IECA 297. but that was the position when the affidavit was sworn. The deponent identifies that distinct expert reports are required to ground professional negligence actions compared to product liability claims. In those circumstances she says that in the timeframe available, the plaintiff issued Ryan 1 as a professional negligence matter only, with secondary product liability proceedings envisaged thereafter.
- 13. In Ms. Power's affidavit, it is explained that when the deponent, as solicitor for the plaintiff, obtained confirmation of the devices inserted into the plaintiff, the plaintiff issued the proceedings in Ryan 2. The deponent identifies that the plaintiff has received confirmation from a biomechanical expert that she has good grounds for a claim against the manufacturers of the devices. She identifies that the manufacturer of the device inserted in 2015, being Astora Women's Health Ireland Ltd. is in administration. In those circumstances she has exhibited a letter from the solicitors who are acting for

the defendant in the administration indicating that the company has been dissolved and that they have no authority to accept proceedings on behalf of the company. Neither solicitor nor counsel appeared in respect of the motion. However, there is an affidavit proving service of the motion on the solicitors for the fifth defendant and in those circumstances, I am satisfied I can proceed to decide this motion against them in their absence.

- 14. Returning to the grounding affidavit, the deponent avers at paragraph 12 that where there is an overlap of evidence between the two Ryan cases, and likely shared witnesses in respect of the consequent medical injuries suffered arising from the mesh devices inserted, it is appropriate to consolidate the two sets of proceedings. She avers that no prejudice has resulted from the consolidation and that it will narrow the issues to be tried at the hearing of the matter.
- 15. All the defendants in the Ryan 1 proceedings support the consolidation. Counsel for the sixth defendant points to the fact that there is what he described as a significant and crucial advantage to consolidation i.e. that if proceedings are consolidated the defendants can serve notices of indemnity and contribution *inter se*, whereas if the two sets of proceedings remain separate, then the defendants will be obliged to either bring separate contribution proceedings or to seek joinder of the manufacturers as third parties in Ryan 1. Counsel for the third named defendant, the HSE, argued that where both sets of proceedings arise out of the same facts and are

referable to the same injuries, then it is difficult to see why the issues should be litigated in separate sets of proceedings.

# Ethicon's objection to consolidation

- 16. On the other hand, the first defendant in Ryan 2 i.e. Ethicon, who manufactured the device inserted in 2012, opposes the consolidation. No replying affidavit was filed in this case but in the other matter before me, Brennan (addressed below), Ethicon filed a replying affidavit of Mr. O'Neill solicitor, of 14 December 2022, objecting to consolidation. The approach taken in that affidavit is, it is fair to say, similar to the opposition voiced by counsel in respect of the application to consolidate in Ryan.
- 17. In short, counsel makes the case that Ryan 1 relates to two separate courses of treatment and that advice was provided to the plaintiff by two different consultants at two different hospitals in 2012 and 2015 respectively. She points out that there can be no liability of Ethicon in relation to the 2015 procedure as their product was not used. She identifies that the evidence to be adduced and the test to be applied in relation to allegations of medical negligence and allegations of a defective product are markedly different, with little or no overlap between the evidence to be given in respect of such differing allegations. She argues that the evidence in respect of Ryan 1 will relate to the standard of care to be met by treating surgeons and is a medical negligence case, whereas the evidence in respect of Ryan 2 would be expected

to relate to technical matters in terms of the products supplied. She criticises Ms. Power for failing to identify the specific nature of overlap of evidence between the two cases and the likely shared evidence.

18. In relation to costs she says there would be no saving of costs to Ethicon by being party to proceedings against medical practitioners in respect of two different courses of care and treatment which occurred several years apart. She argues that Ethicon would be likely to incur significant unnecessary costs in being a party to Ryan 1, given that the evidence will relate to matters not directed towards the plaintiff's allegations of supply of a defective product. She says it would impose a significant time and cost burden on Ethicon which would not be justified by any contribution which Ethicon could make to the evidence of extensive medical negligence allegations.

# **Application of legal test**

19. Applying the *Duffy* test, the first matter I must consider is whether there is a common question of law or fact of sufficient importance. In the written legal submissions filed by the plaintiff, it is argued that there are three common legal questions and one factual one. The first legal question is the extent to which the medical defendants' clinical actions can be distinguished from their provision of the device *qua* intermediary to the plaintiff. The second is that the plaintiff has pleaded that the medical defendants failed to warn her of the nature of the product and associated risks, risks that the manufacturers ought

to have been aware of and which ought to have been conveyed to doctors inserting those devices. She says the level of information available to the medical defendants from the manufacturing defendants, and the consequent liability, is a question of law that falls to be considered in this case. She argues that in the context of her plea of a lack of informed consent, these issues will require to be considered by the trial judge.

- 20. The third common legal question is identified as being the contractual pleas pleaded against the medical defendants in this case. This is a point of distinction between the Ryan and Brennan cases. In Ryan, the plaintiff was treated privately and therefore has a breach of contract claim against the defendants in Ryan 1 in respect of the provision of an allegedly defective device. On the other hand, Ms. Brennan was treated publicly and has no breach of contract claim. I have identified above the contractual pleas against the defendants in Ryan 1. There is no doubt but that they put in issue the suitability and nature of the devices inserted, both in 2012 and 2015.
- 21. In relation to the common question of fact, the plaintiff argues that the trial judge will be required to identify the nature of the plaintiff's alleged injuries, if any, identify the causative factors of that injury, identify the prognosis of the plaintiff and assess damages (if satisfied of liability and causation) and that the resolution of those questions will involve the defendants in both Ryan 1 and Ryan 2.

- 22. That last consideration alone is in my view a sufficient reason to direct the consolidation of these proceedings. The trial judge is faced with a plaintiff who claims an injury that she suffered was caused and/or contributed to, both by the alleged deficiencies in the devices implanted in her <u>and</u> in the manner in which they were implanted, and her care and treatment thereafter. The resolution of that claim will potentially involve the following potential questions:
  - Whether the plaintiff was injured;
  - If so, how any injury was suffered;
  - Whether her injury was caused by one or multiple factors;
  - The interaction, if any, between those factors;
  - Who bears the responsibility for those factors and in what proportion;
  - How much she should be compensated;
  - The appropriate apportionment of compensation, given the relative degrees of involvement of persons found to have caused or contributed to her injuries.
- 23. These questions raise issues of both fact and law and in my view, they are common to both Ryan 1 and Ryan 2. It is difficult to understand how these questions can be satisfactorily answered in the absence of either the medical practitioners/hospitals where the procedures and follow-on care took place, or in the absence of the manufacturers of the device. Ethicon argues that the

claim is best determined in two separate judicial processes. But to separate the component aspects of the plaintiff's claim would inevitably lead to a judge being required to determine the matter without having before them all the constituent parts of the story. To ask a court to determine these questions in the absence of certain of the parties would in my view be to hobble the judge in their ability to address the case in a complete and fair manner. That approach would undoubtedly in my view at a minimum cause confusion, and might even result in a miscarriage of justice.

- 24. In Ryan, there is also an additional factor i.e. that the Court is required to determine the adequacy of the devices as against the medical defendants due to the breach of contract claim. The notion that that could be done in the absence of the manufacturers is fanciful. The manufacturers would in any case be obliged to participate in the trial in some fashion to permit this claim to be adjudicated, whether as witnesses or third parties.
- 25. Finally, there is the plea in relation to informed consent. That is very likely to necessitate the defendants in Ryan 1 identifying precisely what they understood to be the risks involved in the procedure, which requires a consideration of their knowledge of the medical devices and the risks of same, which in turn raises the issue of their relationship with the manufacturers and the provision of information by the manufacturers to them. It seems very likely that the presence of witnesses from the manufacturers will be required in this respect. Again, for the Court to determine this issue in the absence of

the manufacturers as a party in these proceedings is to hamstring the ability of the Court to determine the matter fairly and comprehensively in the light of all relevant evidence.

- 26. Equally, although no defences have been filed by the defendants yet in either set of proceedings, as identified by counsel for the sixth defendants, it is very likely that the medical defendants in Ryan 1 will seek recourse against the manufacturers. It is desirable that should be done in one set of proceedings, whether in a unitary or modular fashion, as opposed to in separate or third-party proceedings.
- 27. In the circumstances I am satisfied I can answer affirmatively two of the *Duffy* questions i.e. there are common questions of both law and fact across both sets of proceedings, and there is a likelihood at the very least of confusion and possibly a miscarriage of justice if the cases remain separate.
- 28. In relation to the third consideration, i.e. whether there would be a substantial saving of expense or inconvenience, I am equally satisfied that having one set of proceedings rather than two will, considered in the round, save costs and be more convenient. Of course, the answer to whether there will be a saving of costs depends in part on whose costs one is considering. Counsel for Ethicon is probably correct in saying that the costs incurred by Ethicon in a consolidated hearing are likely to be higher than the costs that would be incurred in the Ryan 2 proceedings simply because the consolidated proceedings may take longer. But that is to ignore a number of factors.

- 29. First, it only looks at the question of the saving of costs from the point of view of one party i.e. Ethicon, and I must look at costs from the point of view of all parties. From the plaintiff's point of view, it is likely to be less costly to have one set of proceeding than two. Second, Ethicon appear to have failed to take into account other costs that may be incurred by it if the proceedings remain separate i.e. its costs in Ryan 1 if the defendants in that case join them as third parties, or its costs in separate contribution proceedings brought by those defendants. Third, Ethicon treat the question of costs as immutable i.e. they are asking me to assume they will bear their own costs in full irrespective of the outcome of any consolidated proceedings. But if, at a consolidated hearing, the plaintiff is unsuccessful against Ethicon, and successful against the other defendants, then Ethicon would be entitled to seek its costs as against all the other defendants. That is not an option that would be open to it in Ryan 2 should the proceedings remain separate.
- 30. In conclusion, it appears to me that where there are common issues of fact and law as identified above, it is more likely that there will be a saving of costs where they are dealt with together as opposed to in two separate sets of proceedings. A similar consideration applies in respect of the convenience of the matter. Certainly, from the plaintiff's point of view and that of the other defendants, it is more convenient to have all matters dealt with together in the one case. Ultimately it seems to me that it will be more convenient for Ethicon also.

31. In the circumstances I will grant the relief sought.

## BRENNAN

#### **Factual Background**

- 32. Very similar considerations apply in relation to the Brennan case, although the facts are somewhat different. The plaintiff had three vaginal deliveries and postnatally suffered from stress incontinence. She was advised to undergo surgical intervention by way of TVT repair whereby the third named defendant's product; Gynecare TVT laser, was inserted into her pelvic cavity by the first defendant in the second defendant's facility at Kerry General Hospital on 26 March 2009. It is pleaded that she suffered severe and significant pain and discomfort following that operation and was restricted in her mobility and had to attend Kerry General Hospital to identify the source of her debilitating pain. In 2015 she attended the fourth named defendant, a consultant obstetrician and gynaecologist at Kerry General Hospital. He confirmed a section of Ethicon's product was protruding through the plaintiff's vaginal wall. He did not advise it should be removed but advised it should be trimmed. On 15 October 2016 the product was removed in Manor Hospital in Oxford.
- 33. Arising from the circumstances above are two sets of proceedings which the plaintiff now seeks to have consolidated by way of Notice of Motion dated 9 September 2022 grounded on an affidavit of Melanie Power, solicitor, of 9

September 2022. On 14 December 2022, Ronan O'Neill, solicitor for the defendant, swore a replying affidavit.

- 34. The first of these proceedings is entitled *Brennan v Paul Hughes & Ors* Record No. 2017/10245P ("Brennan 1") and was issued on 14 November 2017. The defendants in those proceedings are Paul Hughes, the HSE, and Richard Horgan. The Indorsement of Claim alleges that the first and second defendants are jointly and severally liable for negligence and breach of common law and statutory duties in respect of the procedure identified above and the consequent injuries and loss suffered by the plaintiff. It is further alleged that the fourth defendant negligently failed to provide the plaintiff care to an adequate standard.
- 35. The second set of proceedings bear the title *Brennan v Ethicon PR Holdings Unlimited Company* Record No. 2018/9902P ("Brennan 2") and were issued on 14 November 2018. The personal injuries summons was renewed by Order of Murphy J. on 11 November 2020. The Indorsement of Claim contends that the defendant negligently, and in breach of statutory and common law duties, *inter alia* supplied a defective medical device causing the plaintiff harm.
- 36. As identified above, no contractual claim is made against the defendants in Brennan 1 as the plaintiff was a public patient. However, the same lack of informed consent pleas are made in the updated particulars of loss delivered 7 November 2019 where it is pleaded that the defendants failed to inform the plaintiff of the potential risks and/or long-term complications that could arise

from the use of the product and that the said device was of a permanent nature carrying with it additional risk factors and complications should an issue arise.

37. Unlike in the previous case, the HSE have filed a defence whereby it is pleaded *inter alia* that:

"c. The Plaintiff claims inter alia continuing pain due to, inter alia, scarring from Gynecare TVT. In the event it is proved the said sling was defective or not fit for purpose but the Plaintiff has elected not to pursue the produces and/or supplier of the said tape in these proceedings, the Defendant shall rely upon, inter alia, section 35 of the Civil Liability Act 1961 at the hearing of these proceedings to fix the Plaintiff with the degree of liability of the producer and/or supplier whom the Plaintiff has chosen not to pursue in these proceedings and/or against whom the Plaintiff's cause of action has expired.

d. Without prejudice to the foregoing, if the Plaintiff has sustained the injuries alleged, which are not admitted, and if the said injuries have arisen by reason of the use of Gynecare TVT, which is not admitted, then this Defendant is entitled to an indemnity and or a contribution amounting to a full indemnity from the producer and/or supplier of the said sling,"

# **Notice of Discontinuance**

- 38. Again, all defendants apart from Ethicon are consenting to the motion to consolidate. Ethicon makes the same arguments against discontinuance as it made in Ryan and my conclusions in that context apply with equal force here. However, in opposing consolidation, as identified in the affidavit of Mr. O'Neill of 14 December 2022, Ethicon also relies heavily upon the fact that it had previously been a defendant in Brennan 1 and that a Notice of Discontinuance had been filed against it letting it out of those proceedings.
- 39. The sequence of events in this respect is well set out in an affidavit Ms. Power sworn on 3 November 2020 in support of a renewal of the summons in Brennan 2. The Brennan 1 proceedings were issued on 14 November 2017. The Brennan 2 proceedings were issued on 14 November 2018. On 4 December 2019, the plaintiff issued a Notice of Discontinuance against Ethicon in Brennan 1. Ms. Power identifies that she included Ethicon as a defendant in Brennan 1 on the basis that the device inserted in the plaintiff was known to her as one made by Johnson & Johnson, and she had identified the defendant as a potentially connected party within the Johnson & Johnson medical device empire. She says she wrote to Ethicon seeking clarity in this respect but only received a reply from Ethicon on 9 July 2020. She avers she had no forensic evidence as against Ethicon and therefore decided to issue secondary product liability proceedings so she could benefit from the further 12 month limitation period afforded to such proceedings. Once the Brennan 2 proceedings were issued, she issued a Notice of Discontinuance in Brennan

1 to avoid two sets of proceedings being extant in relation to the same device. In June 2020 she obtained professional evidence that the devices were defective. She then sought to renew the summons in Brennan 2.

- 40. In his affidavit, Mr. O'Neill avers that he did not understand why proceedings had been discontinued against his client but at the hearing counsel for Ethicon accepted that an explanation had been given by counsel for the plaintiff, while maintaining her objection to consolidation on the basis of the discontinuation. The precise nature of the legal objection has not been identified. For example, it was not argued that the plaintiff is estopped from seeking consolidation. Ethicon simply argues that by reason of the discontinuance, the plaintiff should be denied the benefit of consolidation. Counsel for the plaintiff accepts that matters proceeded in an unusual way but argues that these are difficult proceedings for the plaintiff to bring, being a hybrid type claim combining claims for medical negligence with claims for defective products. She argues that the differing limitation periods and the necessity for PIAB authorisation at the time in respect of device litigation, as well as the difficulty in obtaining expert evidence, explains and excuses the unorthodox procedural approach here.
- 41. It seems to me that the somewhat involved procedural background does not alter the legal test to be applied when considering whether matters should be consolidated. For the reasons I set out above in Ryan, I consider there is a common issue here both of fact and law i.e. the fact that the plaintiff's injuries

and the cause of same is common across the two sets of proceedings. Indeed, the argument in relation to the involvement of Ethicon in the clinical negligence proceedings is even stronger here where a defence has been filed by the HSE putting in issue the liability of Ethicon. The plea of informed consent additionally means that the Court will be required to examine in the context of this question the relationship between the medical defendants and the manufacturing defendants.

- 42. Again, for the same reasons identified in Ms. Ryan's case, I consider that to have one set of proceedings will result in a saving of costs and will be more convenient for all parties taken in the round. One set of proceedings will likely result in a saving of judicial time and that too should be taken into account.
- 43. In those circumstances, the fact that the plaintiff could have avoided the necessity for a consolidation motion had she kept Ethicon in the Brennan 1 proceedings should not in my view prevent access to the undoubted advantages afforded by consolidation. In the circumstances I will direct consolidation of the Brennan proceedings.
- 44. Nonetheless, Ethicon's point that the motion could have been avoided had the plaintiff acted differently is one that may be relevant to the costs of this motion, including the plaintiff's reasons for the course of conduct adopted. I will hear submissions on this point when costs are being adjudicated.

22