Europe *Netherlands*

Multi-component products: expiry period for damages claims

Introduction

On 17 December 2019, the Court of Appeal of Arnhem-Leeuwarden (the "**Court of Appeal**") handed down an interesting judgment on the expiry period applicable to the right to claim for damages in a matter involving an alleged defective product. In this case, the product consisted of four components that had been put into circulation on different dates by the same manufacturer.

Facts

On 24 September 2004, a patient underwent surgery during which an orthopaedic surgeon inserted a hip prosthesis into his body. The hip prosthesis consisted of four separate components; (i) a cup placed in the pelvis, (ii) a head that rotates in that cup, (iii) a taper adaptor, and (iv) a stem.

Each component was manufactured and delivered to the hospital on different dates. The head, taper adaptor and cup together are called the hip system. The hip system together with the hip stem forms the hip prosthesis.

Following various health complaints, the patient underwent a blood test and on 27 February 2012, the results showed an increase in cobalt and chromium values. As the pain continued, a hip revision surgery took place on 20 July 2012 during which the hip system of the prosthesis was replaced but the stem was not removed.

After the hip revision surgery, the cobalt and chromium values in the patient's blood decreased significantly. However, the patient's complaints of persistent pain continued. As a result, the patient was seen by a rehabilitation doctor on 18 April 2013. The doctor diagnosed the patient with a pelvic misalignment and a difference in leg length. On 27 September 2013, a second hip revision took place.

The patient claimed that the manufacturer of the hip prosthesis should be held liable for the damages allegedly suffered (along with future damages) as a result of the implantation of the hip prosthesis. The patient therefore issued a writ of summons on 19 May 2014.

Interim judgment at first instance

Under Article 6:191(2) of the Dutch Civil Code ("**DCC**"), an injured person's right to damages against a manufacturer as per Article 6:185, paragraph 1 DCC, is extinguished at the end of the expiry period. The expiry period is currently 10 years, beginning on the day after the date that the manufacturer put the product that caused the alleged damage into circulation, unless the injured person has begun proceedings against the producer in the meantime. This provision implements Article 11 of the Product Liability Directive ("**PLD**").[1]

At first instance, the manufacturer argued that the head had been put into circulation on 5 May 2004 (the date it was delivered to the importer) and that the claimant's right to claim damages in relation to the head had therefore expired on 5 May 2014. On that basis, according to the manufacturer, the claimant's right to claim alleged damages for the hip system as a whole had also expired.

According to the claimant, the damage could not have been caused by the components individually. Instead, damage resulted when the components came together as an end-product (i.e. the cup and head had functioned defectively together).

The claimant therefore argued that the expiry period only started to run the day after the operation, given that the components of the prosthesis were not actually assembled into an end-product – the hip prosthesis – until the operation took place.

The District Court agreed with the claimant: the product could only be considered to be a product that could cause damage when its four different components were combined into one single product (the hip prosthesis).

The District Court therefore ruled that the claimant's right to claim damages had not ended 10 years after the head had been put into circulation. This was because the other three components' periods had not expired on the day the writ of summons was issued.

The manufacturer appealed the decision to the Court of Appeal.

1 Directive 85/374/EEC

Court of appeal judgment

The manufacturer appealed, arguing that the expiry period started separately for each component, depending when they were put into circulation. The head was the first component put into circulation on 11 February 2004.[2] Accordingly, the manufacturer argued that the expiry period began on 12 February 2004. That meant the claimant's right to claim damages had expired 10 years later (on 11 February 2014).

The manufacturer also argued that (i) it could not qualify as the manufacturer of the hip prosthesis, (ii) it did not put the end-product into circulation and (iii) it was not involved in the implantation of the end-product into the claimant's body.

The Court of Appeal's deliberations and decisions are interesting, both in relation to the interpretation of the terms "manufacturer" and "date of putting into circulation" (as defined in the DCC/PLD), and in regards to the question of whether the expiry period of one component impacts the expiry period of the end-product as a whole.

"Manufacturer" and "date of putting into circulation"

The Court of Appeal ruled that the date of the claimant's operation could not be considered to be the date on which the components were put into circulation. This would run contrary to the 2006 ruling of the Court of Justice of the EU ("**ECJ**") in *O'Byrne/Sanofi*[3] and the ECJ ruling of *Centre hospitalier/Dutrueux* on 21 December 2011.[4]

In O'Byrne/Sanofi, the ECJ ruled the following with regard to the date of putting into circulation:

> "27. In light of those considerations, a product must be considered as having been put into circulation, within the meaning of Article 11 of the Directive, when it leaves the production process operated by the producer and enters a marketing process in the form in which it is offered to the public in order to be used or consumed. 28. Generally, it is not important in that regard that the product is sold directly by the producer to the user or to the consumer or that that sale is carried out as part of a distribution process involving one or more operators, such as that envisaged in Article 3(3) of the Directive."

In *Centre hospitalier/Dutrueux*, where a patient had suffered from burns caused by a defective mattress in a hospital, the ECJ ruled:

> "In the present case, the liability that may be incurred by a user which, like Besançon CHU, employs, in the course of providing treatment to a patient, a product or equipment that it has previously acquired, such as a heated mattress, is not among the matters regulated by Directive 85/374 and hence does not fall within the directive's scope."

In the case at hand, the Court of Appeal ruled – without any further clarification – that the hospital where the hip prosthesis was inserted into the patient could not be regarded as the manufacturer (or importer or supplier) within the meaning of Article 6:187 DCC.

Therefore, according to the Court of Appeal, the expiry period under Article 6:191(2) DCC did not start at the date of surgery (as the start of the expiry period is explicitly linked to the moment at which the manufacturer puts the product into circulation). The Court of Appeal ruled that the "date of putting into circulation" was in fact the date when the components were received by the importer, because this was the moment when the components left the production process operated by the manufacturer and entered a marketing process in the form in which they were offered to the public for use or consumption.

2 In first instance, the manufacturer had stated that this was 5 May 2004, but this was corrected on appeal.

3 European Court of Justice 9 February 2006, C-127/04, *NJ* 2006/401 *(O'Byrne/Sanofi).*

4 European Court of Justice 21 December 2011, C-495/10, ECLI:EU:C:2011:869 *(Centre hospitalier/Dutreux).*

Expiry period prolonged

On the question of receipt of the four components by the importer, the Court of Appeal noted that the first date of receipt (of the head) was 11 February 2004 and the last date of receipt (of the taper adapter) was 18 August 2004.

Accordingly, there was a difference of six months between the dates of receipt of the four components. The key question to be answered by the Court of Appeal was whether expiration of the expiry period of the first component put into circulation also meant that the expiry periods of the other three components had also expired.

The Court of Appeal observed that this specific question had not previously been addressed in the case law of the ECJ or of the Dutch Supreme Court. It therefore quoted the Opinion of Advocate General Trstenjak in the *Aventis/O'Byrne* case.[5] Trstenjak had argued that each of the components of an end-product put into circulation by different manufacturers has its "own" expiry period, stating:

> "106. If several producers or suppliers to be classified as producers form part of a chain of value creation, the time when the limitation period starts running must be ascertained separately for each producer. If, then, proceedings brought against one producer or supplier to be classified as a producer interrupted the expiry period in relation to all the other producers and suppliers to be classified as producers involved, regardless of whether they were ever made parties to the proceedings or even became aware of them, that could scarcely be reconciled with the approach followed in O'Byrne of examining the particular individual case."

As the Court of Appeal observed, if one followed this line of reasoning, it would also apply to the expiry periods of components of an end-product, even if those components had been manufactured by the same manufacturer. That would mean that the expiry period for each component ran separately and, as a result, the patient's claim in this case should have been rejected.

In this case, however, it had not been stated or shown that one of the components of the prosthesis was defective. Rather, it has been claimed that the alleged defectiveness of the hip prosthesis (as an end-product) was caused by friction between the head and cup. Accordingly, the conclusion arrived at in *Aventis/O'Byrne* would be unworkable in practice and would lead to an undesirable result. The Court of Appeal therefore decided that because the case before it concerned an end-product consisting of several components (the hip prosthesis), each of which had been put into circulation by the same manufacturer but on different dates, and given that the alleged defectiveness was caused by the combination of two of those components (the head and cup), the expiry period of the end-product began when the last of those two components (the cup) was put into circulation (7 August 2004).

Following this reasoning, the Court of Appeal stated that it had achieved a balance between protecting the consumer, who has an interest in bringing the defect caused by a combination of components before a court of law, and the manufacturer, who has an interest in a clear end date of the expiry period (and of its liability).

The Court of Appeal therefore concluded that at the time the writ of summons was issued (19 May 2014), the expiry period of the hip prosthesis had not yet expired.

Comment

It is questionable whether the decision that the hospital/surgeon does not qualify as the manufacturer of the hip prosthesis would be upheld on appeal in cassation. The only substantiation given by the Court of Appeal on this point was its reference to the ECJ's ruling in *Centre hospitalier/Dutreux*.

In that case, the product (a defective mattress) was already an end-product when it was delivered to the hospital. However, in the case before the Court of Appeal, the end-product hip prosthesis) had been formed when the hospital/surgeon combined the four separate components.

5 European Court of Justice 2 December 2009, C-358/08, ECLI:EU:C:2009:744 (Aventis/O'Byrne).

Additionally, it seems arbitrary to decide that the expiry period for the end-product began when the last component of the two components causing the alleged defectiveness (the cup and stem) was put into circulation (the cup). It appears that this decision was inspired by the Court of Appeal's apparent desire to achieve a claimant-friendly result.

Contrary to what the Court of Appeal stated, this outcome is not in the interest of legal certainty (a clear end-date for the expiry period) for the manufacturer. In some cases, it could, in fact, lead to expiry periods much longer than the 10 years stipulated in the PLD (and the DCC).

By way of example, say one of the components of the hip prosthesis was replaced several years later by a new component (which has been put into circulation at a much later date than the other components). That new component, together with one of the other, much older, not-replaced components, then causes the alleged defectiveness. Following the Court of Appeal's judgment, this would mean that the expiry period for the other components was prolonged by years – as opposed to days or months like in the current case. Perhaps it is for this reason that the Court of Appeal specifically stated that its decision achieved a balance between the interests of the consumer and the manufacturer in this case.

The manufacturer has three months from the date of this judgment to lodge an appeal with the Supreme Court of the Netherlands.

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