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COMMENTARY

Brexit: Product Regulation and Safety–Further Musings on the Possible Effects on Importers of Goods into the European Union

As this *Commentary* went to press, the UK Supreme Court's decision as to whether the British Government must consult Parliament over the timing and manner of the country's withdrawal from the European Union had yet to be issued. A lower court decision has held that it must do so, but Prime Minister May's Government insists that it does not need to consult lawmakers, being instead able to invoke Article 50 of the Lisbon Treaty (the withdrawal provision) by use of the prerogative powers (*see* Jones Day Emerging Issues Video, "Impact of the High Court Decision on Triggering Article 50").

It is important to realise that these court referrals relate only to what is the correct mechanism by which Article 50 can be invoked—not whether it should be invoked.

Both main political parties in the United Kingdom are committed to Brexit. A vote in the House of Commons on 7 December 2016, recorded a majority of 37 MPs in favour of committing the Government to invoke Article 50 by its own preferred date of sometime in March 2017.[1]

Whilst there is still little detail of what the process of withdrawal might lead to (in terms of changes to/differences between product regulation and safety rules in the European Union and the United Kingdom post-separation), some commentators feel that a clue may have been given recently by reference to patent law.

This clue was the decision of the United Kingdom to carry on with the ratification of the Unified Patent Court Agreement ("UPCA") as if the Brexit vote had not happened (*see* Jones Day *Alert*, "European Unitary Patent Court—Back on Schedule for 2017").

Might this suggest there may also be a desire to see "no change" to product safety and regulation regimes post-Brexit? At this stage nobody knows, but in this *Commentary*, our product liability lawyers consider further possibilities.

Doing Business

The news in October 2016 that the Japanese auto manufacturer Nissan has apparently committed to investment in its UK plant for the production of two new models[2] led to a flurry of speculation as to what assurances of business continuity the company had

sought/been given. The press reported that other auto manufacturers that also make the United Kingdom their European Union manufacturing base would likely seek similar comfort, whatever that comfort had been.

To date, however, the nature and extent of assurances given by the UK Government (if any), and to whom, remain in the realms of speculation. No details have emerged.

The news cycle has moved on to focus its attention upon the tech sector, with announcements that Google and Facebook, for example, also intend to make significant investments in the United Kingdom, irrespective of Brexit uncertainties.[3]

The news of all such investment has been taken by the British press as an indication of continuing confidence in the United Kingdom. Of course, even once it has exited the European Union, the United Kingdom, as one of the world's largest economies,[4] will continue to be a major market for such goods and services.

The same is true as regards all other manufactured goods, in relation to which access to the UK market surely is of sufficient importance to require importers to stay abreast of likely changes.

Are there any further pointers that can be given at this time to help importers in relation to additional burdens that may be imposed by the separation of the two markets?

Let us consider.

Challenges

Harmonisation. Manufacturers and importers of products for which there is sector-specific EU harmonisation legislation must comply with the specific safety, health and environmental requirements stemming from all such harmonisation legislation applicable to the product, in addition to the requirements of the Product Liability Directive and the General Product Safety Directive. The body of sector-specific EU harmonisation legislation is extremely broad and ranges from requirements on medical devices to radio equipment and from low-voltage electrical goods to toys.

Compliance with all applicable EU harmonisation legislation in relation to a product is generally attested by the manufacturer or its authorised representative by affixing the "*Conformité Européenne*" (European Conformity) "CE" mark to the product. A validly affixed CE mark allows the product to be sold throughout the European Economic Area ("EEA") (i.e., the 28 EU Member States plus Iceland, Liechtenstein and Norway) without restrictions.

The requirement to comply with EU harmonisation legislation and affix CE marks, where mandated, also applies to imported products that are sold in the EEA. Unauthorised or misleading use of CE marking may result in penalties, including criminal sanctions for serious infringements.

If Brexit involves the United Kingdom departing from the EEA, then CE-marked products may not be able to be sold into the United Kingdom automatically.

The European Union's CE regime is currently applicable in England, Wales, Scotland and Northern Ireland by virtue of the EU Regulation on Accreditation and Market Surveillance (765/2008), which is directly applicable in UK law. As directly applicable EU regulations are seemingly to become incorporated into UK law on Brexit Day 1, by virtue of the Great Repeal Bill (*see* our previous *Commentary*), this presumably means that as of Brexit Day 1, nothing should change (that is to say, a CE-marked product should be capable of lawfully being sold in the United Kingdom), but one cannot presently predict how matters will develop. Any movement away from the current status quo could prove a considerable dislocation.

Another issue around CE marking concerns so-called "Notified Bodies" or "NBs". These are conformity assessment bodies appointed by national authorities to carry out the procedures for conformity assessment within the meaning of the applicable harmonisation legislation.

Post-Brexit, UK NBs may no longer be entitled to conduct such conformity assessments or may have to clear additional hurdles to do so. Nobody knows, but If that is so, then manufacturers/importers working with UK-based NBs may be required to appoint an alternative NB established in an EEA Member State.

Authorised Representatives. Another potential uncertainty concerns EU legislation of the type that requires non-EU based operators to appoint an "authorised representative" established in the European Union.

An example of one such piece of legislation is the Cosmetic Product Regulation (1223/2009) ("CPR"), which is presently directly applicable in the United Kingdom as an EU Member State and lays down rules as regards the manufacturing and import of cosmetic products.

The CPR requires non-EU manufacturers to appoint a "responsible person" within the European Union. Non-EU companies using UK-based authorised representatives may need to rethink this and appoint a responsible person in one of the remaining Member States following Brexit.

Another example is the Medical Devices Directive (93/42/EEC), which requires non-EU manufacturers to designate a single authorized representative in the European Union. This Directive is implemented into UK law through the Medical Devices Regulations 1994 S.I. nº 3017 of 1994.

National Interests. Similarly speculative at this stage is the question of how the United Kingdom might choose to develop its own historic safety concerns which, for whatever reason, have not been taken up as EU concerns.

Some commentators feel that this seeming lack of concern at the supranational level has deterred the United Kingdom from taking such matters forward. The question is therefore whether, when there is no longer a supernational dimension, the United Kingdom may feel it appropriate to take a more aggressive stance in its own national legislation.

For example, some flammability regulations for textiles (nightwear, etc.) have concerned the United Kingdom (and Eire) but not attracted the attention of Brussels. When no longer within the European Union, might the United Kingdom decide to legislate on its own, thus causing further disconnect for importers?

When Will There Be Clarity?

Writing in the *FT*'s "Comments" section last month,[5] Wolfgang Münchau put it succinctly when he said, "The truth about the impact of … Brexit is that it is uncertain, beyond the ability of any human being to forecast, and … almost entirely dependent upon how the process will be managed".

That all-important piece of the jigsaw (how the process will be managed) is not yet clear but, one hopes, will become more so in the light of the 7 December 2016 Commons vote, which called for a "Brexit Plan" as "Article 50 day" (a date in March 2017?) approaches.

Until then, as Münchau points out, the technically correct answer to the question "What is going to happen?" is "I don't know".

Since that may not be the most helpful of answers for importers, Jones Day's product liability lawyers worldwide will continue to track and anticipate developments so that when they occur, and when the numerous issues begin to assume some shape and form, we are able to counsel our manufacturing clients and contacts on their new world as it unfolds.

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Endnotes

1 *The Independent*, 8 December 2016.

2 FT, 5 and 16 October 2016.

3 *The Telegraph*, 15 and 21 November 2016.

4 Fifth by GDP. Source: World Bank 2015 statistics.

5 FT, 28 November 2016.