# exchange control and clinical trials agreements

In recent months we have encountered uncertainty on the part of some authorised dealers and legal advisors in relation to the issue of obtaining exchange control approval for clinical trial agreements.

This uncertainty finds its origin, in part, in the use of the term “intellectual property” (“IP”) in the South African Exchange Control Regulations promulgated under the Currency and Exchanges Act No. 9 of 1933 (as amended) (the “Regulations”).

Regulation 10(1)(c) of the Regulations provides that:

> *“No person shall, except with permission granted by the Treasury and in accordance with such conditions as the Treasury may impose – (c) enter into, any transaction whereby capital or any right to capital is directly or indirectly exported from the Republic."*

There was for many years debate about whether intellectual property was included in the term “capital” as used in Regulation 10(1)(c) and as a result debate about whether IP transactions such as sales, assignments, transfers and licences of intellectual property require exchange control approval.

This debate was finally brought to a close when the Exchange Control Regulations were amended with effect from 8 June 2012. The amendment introduced a new regulation 10(4), which provides that for the purposes of Regulation 10(1)(c):

> *(a) ’capital’ shall include, without derogating from the generality of that term, any intellectual property right, whether registered or unregistered; and*
>
> *(b) ’exported from the Republic’ shall include, without derogating from the generality of that term, the cession of, the creation of a hypothetic or other form of security over, or the assignment or transfer of any intellectual property right, to or in favour of a person who is not resident in the Republic.*

The challenge that we face when dealing with clinical trials programs is to determine what is meant by intellectual property within the context of regulations 10(1)(c) and 10(4). Although it is certain that registered IP such as patents, designs, trade marks and plant breeders’ rights, as well as unregistered IP such as copyright works fall within the ambit of regulation 10(1)(c), it is arguable that other intangibles having a commercial value to the possessor also fall within the category of unregistered IP rights. These other unregistered intellectual property rights would include trade secrets, confidential information and know-how.

There is a trend around the world to broaden the definition of intellectual property beyond the traditional areas of patents, trade marks, copyright, registered designs and plant breeders rights. Know-how is considered by many countries to fall squarely within the ambit of intellectual property (see for example Phillips v Mulcaire [2012] UKSC 28).

There is a growing recognition that intellectual property protection is required over know-how and trade secrets in certain industry sectors. Clinical trials is one of the areas that is at the centre of this debate, recognising the tremendous value and commercial advantage that clinical trials data provides to the funder of the trial. An example of this trend is the European Parliament which is considering a directive on “the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure”.

When dealing with South African Exchange Control Regulations our advice to clients is to take a conservative view on the interpretation of the term “intellectual property”, particularly when one considers the severe consequences of non-compliance weighed against the relatively straightforward process of securing the necessary exchange control approvals.

Clinical trial agreements typically provide for clinical trial data to be transferred to the sponsor, as well as inventions, copyright in notes and reports. All of these are intellectual property within a broader definition of intellectual property and as such Exchange Control approval is required for the transfer of these rights and the data sets to the sponsor.

Another common mistake that we have encountered in respect of clinical trial agreements is that these agreements are being motivated to authorised dealers as pure services agreements in an attempt to construct an argument that exchange control approval is somehow not required for the intellectual property aspects of clinical trials agreements. In this regard it is important to note that the Regulations apply to the transfer of capital, irrespective of whether the transfer of capital is wound-up in a broader services agreement. Accordingly, a services agreement that contains a transfer of capital in the form of intellectual property will still be subject to obtaining exchange control approval.

In conclusion, our advice to our clients when dealing with clinical trails agreements sponsored by off-shore companies or agencies is to take a conservative view on the interpretation of the term “intellectual property” and ensure that any transfer of intellectual property rights and data sets under the agreement has the necessary exchange control approvals. This is particularly so when one considers the severe consequences of non-compliance, weighed against the relatively straightforward process of securing exchange control approval. These adverse consequences include not only the possible invalidity of the agreement, but also extend to financial claims by the sponsor against the South African institutions or universities should the necessary approvals not have been obtained by the South African entity thereby resulting in a possibly invalid agreement.

Should any additional information or assistance be required, please contact us.

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