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The Application of the UK's NSIA to Life Sciences Transactions

Attorneys
Lincoln Tsang
Ruchit Patel
Hannah Kerr-Peterson
Lisa Kaltenbrunner

1. Executive Summary

The UK's National Security and Investments Act ("**NSIA**") came into force today, granting the UK Government, through the Department for Business, Energy & Industrial Strategy ("**BEIS**"), the power to review transactions that may give rise to a national security risk. A mandatory filing under the NSIA is required, with a stand-still obligation until clearance is obtained, if the buyer acquires control or >25% of the shares or voting rights of the Target and the Target is active in one of 17 specified sectors, including *Synthetic Biology* and A*rtificial Intelligence* ("**AI**"). In this alert, we focus on the NSIA's application to life sciences transactions, including acquisitions of firms that may involve in activities relating to synthetic biology and AI, providing guidance on which transaction may warrant a detailed assessment, and which may benefit from an exemption.

For further details on other sectors and application of the NSIA, see September alert.

2. Synthetic Biology

Synthetic biology is the process of applying engineering principles to biology, to design, redesign or make biological components or systems that do not exist in the natural world: in other words, designing biological systems that do not exist in nature. The objective is to generate and assemble functional individual (or otherwise modular) components for the development of novel applications and processes such as synthetic life, cells or genomes.

a) The NSIA captures the following activities in this sector:

- Carrying on basic scientific research into synthetic biology;
- The development of synthetic biology;
- The production of goods using synthetic biology;
- The formulation of synthetic biology to enable the degradation of materials; and
- The provision of services that enable the activities set out above.

b) By way of illustration, the following entities may be within the NSIA's scope:

- Entities providing core services that are related to the (re-)design or engineering of a biological system that falls within the definition of synthetic biology (e.g. companies which synthesize DNA, or are involved in cloning related to core synthetic biology).
- Entities which store sensitive human genetic information that enables the identification of an individual (e.g. biobanks, tissue banks, and blood banks).
- Life sciences entities which own/develop biological or immunomodulatory assets which could be employed or modified to produce or deliver toxic chemicals to achieve an incapacitating or lethal effect on humans or animals, or materials which have been restricted under anti-terrorism or crime and security legislation.

- Entities which conduct industrial biotechnology research, development, or production using enzymes or organisms that have been modified via synthetic biology, for example:
    - Engineering algae as biofactories for renewable fuel; or
    - Biological fertilizers that use genetically manipulated bacteria to fix nitrogen from the air and deliver it to the roots of corn crops.

c) However, the NSIA also exempts certain activities in this sector that would not raise national security concerns:

- Medical diagnostics
- Industrial biotechnology, to the extent that it does not employ synthetic biology
- Bioremediation (i.e., the use of microorganisms to remove or break down harmful contaminants, pollutants or toxins from the environment)
- The production of substances ordinarily consumed as food, i.e. the food itself, but not necessarily products used in its production which are not intended for human consumption, such as fertilizers.
- Life sciences companies' ownership/development of biological or immunomodulatory assets which could not be employed or modified to produce or deliver toxic chemicals to achieve an incapacitating or lethal effect on humans or animals, or materials which have been restricted under anti-terrorism or crime and security legislation.
- Research and development of gene therapy and cell therapy:
    - Gene therapy, i.e., medicinal products containing therapeutic genes that lead to a therapeutic, prophylactic or diagnostic effect. Such an effect is mediated through inserting exogenous genes into the body.
    - Cell therapy, i.e., where human cells are extracted from a patient, modified by genetic engineering, and then reintroduced to treat disease. For example, a specific type of blood cell can be harvested from a patient and genetically manipulated in a controlled environment using a viral delivery system, which carries a copy of the therapeutic gene to treat a particular condition. Another approach would be gene-editing, which uses a biological process to cut out a target sequence of DNA from a cell's genome and replace it with a target DNA sequence.
    - The therapeutic approaches based on gene and cell therapies are capable of treating a variety of rare, life-threatening or debilitating diseases or conditions, including those that may be hereditary.

3. Artificial Intelligence

Companies researching AI or developing or producing goods, software or technology that use AI for the purposes of "*the identification or tracking of objects, people or events*" may also require a mandatory filing. This may capture health tech companies using AI to assess patients – some of which rely upon the collection of real-time information, which could be viewed as "tracking of a person". For example, clinical trials may be conducted using wearable devices with built-in functionalities to collect real-time biometric or physiologically relevant data related to the participants. AI algorithms, combined with an effective digital infrastructure, could enable the continuous stream of clinical trial data to be cleaned, aggregated, coded, stored and managed.

4. Proposed timing of the BEIS review

From acceptance of the filing, BEIS has 30 working days to review the transaction and decide whether to issue a call-in notice. If BEIS issues a call-in notice, it has a further 30 working days (plus an additional 45 working days extension if needed) to review the transaction and reach a decision: either approving, approving with remedies, or prohibiting the transaction. During this review period, the parties cannot complete.

5. Sanctions for not filing

The UK Government can impose interim and final orders, suspending a transaction during its review or requiring a transaction to be unwound following its review. Orders can have extraterritorial effect. Penalties for failure to comply are imprisonment (up to 5 years) and/or fines (the higher of 5% of global turnover or £10m).