Tim Gunn
is a professional development lawyer in Ashurst's London office.

New Technology Transfer Block Exemption and Guidelines: A challenge for biotechnology

Tim Gunn

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Abstract

This paper focuses on the potential impact of the new Technology Transfer Block Exemption (TTBE) on biotechnology firms, particularly with regards to small and medium-size enterprises, and assesses the challenges faced when implementing the new rules. It discusses EU competition law, in particular article 81(1) and 81(3) of the European Community Treaty, and outlines the pro-competitive criteria that undertakings are required to meet in their agreements. It outlines key concepts of the TTBE, including a brief comparison with the 1996 TTBE, and details of how biotechnology licences fit within the scope of the new TTBE. Reference is made to the Commission's Guidelines and the effects of competition on the biotechnology market. The paper also discusses the difficulties faced in gaining exemption and compares those faced by competitors and non-competitors, the importance of market share and provides a list of 'hardcore' and 'excluded' restrictions. Furthermore, the paper contains details of the guidance provided by the Commission on carrying out an individual assessment for parties whose agreements fall outside the block exemption.

Keywords: *biotechnology, block exemption, competition law, European Union, intellectual property, technology*

POTENTIAL IMPACT

Challenging times lie ahead for biotechnology firms, particularly small and medium-sized enterprises (SMEs). The reason is the introduction on 1st May, 2004, of new rules from Brussels.

WHAT EU COMPETITION LAW IS ABOUT AND WHY IT MATTERS

Intellectual property (IP) rights are monopoly rights granted by the state to stimulate innovation, ie national rights. Rights-holders can prevent others from making, using or selling any product covered by these rights and, through licensing, aim to recover their investment and hopefully make a profit as well.

The philosophy behind EU competition law is different. Its goal is to promote competition by increasing the number of players in the market. The anticipated results are cheaper prices and a wider choice for consumers. However, these short-term effects need to be balanced with the longer-term ones. Innovators will cease to innovate if other firms enter the market and take a 'free ride' on the back of the innovator's efforts. Consumer choice may suffer. Consequently, EU case law recognises the pro-competitive nature of licensing and that a licensee may need exclusivity so that it can recover its investment.

EU competition law is also concerned with the creation of the 'single market' – with which national rights can conflict. Consequently, it seeks to facilitate the free movement of goods and services within the EU.

Case law has developed to rationalise these two different systems and holds that a monopoly position is not by itself anti-competitive. It is more concerned with the question of how an undertaking uses the power conferred by that position and whether if it gives rise to abusive conduct. Focusing on licences, the courts state that

Tim Gunn
Ashurst,
Broadwalk House,
5 Appold Street,
London EC2A 2HA, UK

Tel: +44 (0)20 7859 2879
Fax: +44 (0)20 7638 1112
E-mail: tim.gunn@ashurst.com

Restrictions within agreements

any restrictions contained within these agreements should not extend beyond the 'specific subject matter' of the licensed IP rights. Broadly, this means that if the restriction in the agreement goes beyond what the IP rights owner would be able to restrict by virtue of their IP rights alone (ie as distinct from their contractual rights), that restriction is not permitted.

Potential consequences for infringement

The cornerstone of EU competition law is Article 81(1) of the European Community Treaty. In effect this prohibits agreements that have the object or effect of preventing, restricting or distorting competition to an appreciable extent. The potential consequences of breach have significant deterrent value: fines of up to 10 per cent of worldwide turnover, invalidity of the agreement and the prospect of third party damages claims.

Possible exemption from competition law under 'block exemptions' issued by the EU commission

Exemption from Article 81(1) is possible under Article 81(3) of the Treaty. This sets out various pro-competitive criteria that the agreement must meet. The most convenient and certain means of meeting these is to fit your agreement within one of the Commission's 'block exemptions', such as the Technology Transfer Block Exemption (TTBE).[1] Another key provision of the Treaty is Article 82. This prohibits an undertaking that is dominant in the market from abusing its position and no exemption from this is available. UK competition legislation reflects this approach. The Office of Fair Trading now has the right to make observations to the UK courts in cases that involve Article 81 or 82.

Previously, a party to an agreement – which did not fit within the parameters of the (old) TTBE – could notify the Commission to seek an 'individual exemption'. However, the EU's 'modernisation' package came into effect on 1st May (the same date as the new TTBE entered into force), which means Article 81(3) can now be applied directly by national courts and authorities. As a result it is no longer possible to seek individual exemption from the Commission. Instead, national competition authorities (NCAs) and courts will determine whether at the relevant time the agreement was exempt. Commercial disputes between parties in this area are likely to involve a challenge to a licence before the courts. Accordingly, national courts are likely to play a greater role in interpreting the new rules.

If the relevant agreement does not fit within the TTBE, the parties must determine whether the agreement falls foul of Article 81(1) (individual assessment) and if so, whether it is arguable that Article 81(3) (criteria for exemption) applies. This will require a more detailed economic assessment of the agreement. The Commission's Guidelines issued with the TTBE state that exceeding the market share thresholds, while taking the agreement outside the TTBE, does not raise a presumption that the agreements are caught by Article 81(1), or fail to satisfy the conditions of Article 81(3).

KEY DATES AND CONCEPTS IN BRIEF

The TTBE comprises a set of conditions that, if followed, provide a safe harbour for an agreement from the prohibition in Article 81(1). It replaces the formulaic 1996 TTBE[2] with an economic 'effects' based analysis.

The new block exemption is radically different from the old one. It treats agreements between competitors more strictly than those between non-competitors as these are more likely to give rise to competition concerns. It exempts both types of agreements, subject to market share thresholds not being exceeded and also subject to specified banned restrictive terms (referred to as 'hardcore' and 'excluded' restrictions) not being present in the agreement. These are the equivalent of the old 'black' list and there are separate lists of hardcore restrictions for competitors and non-competitors. However, there is no express 'white' list of permitted clauses as under the old block exemption, although some

of the exceptions to the blacklisted restrictions in effect achieve the same purpose.

If the relevant market share threshold is exceeded (in which case 'individual assessment' is required), the parties may potentially enter a second 'safe harbour', if there are four or more independently controlled technologies in addition to those controlled by the parties themselves.[3]

Reasonable certainty that a licence is not in breach of Article 81(1) generally is key for the parties to an agreement and their investors. The 1996 TTBE achieved this. The new block exemption, although in many respects more permissive, provides less legal certainty as a result of the introduction of the market share thresholds. This is explained further below.

KEY FEATURES OF THE BIOTECHNOLOGY INDUSTRY

Application of block exemption dependent on relevant market share and absence of hard core restrictions

Biotechnology is arguably different from other industry sectors. It is also important to the EU economy. The Commission recognised this in 'Life Sciences and Biotechnology – a Strategy for Europe', where it said (emphasis added):

> As probably the most promising of the frontier technologies, life sciences and biotechnology can provide a major contribution to achieve the European Community's Lisbon Summit's objective of becoming a leading knowledge-based economy. The European Council in Stockholm in March 2001 confirmed this and invited the Commission, together with the Council, **to examine measures required to utilise the full potential of biotechnology and strengthen the European biotechnology sector's competitiveness in order to match leading competitors**. . .

Advances in biotechnology will revolutionise medicine – from diagnostics and treatment to detection and prevention. Examples to date include life-saving therapies, such as recombinant factor IX treatment for haemophilia B.

Biotechnology firms, typically SMEs, tend to be highly innovative, but generally lack the resources and infrastructure to carry out late stage clinical trials on new drug candidates or to bring them to market. Typically, the firm will grant a licence to a pharmaceutical company to carry out these activities in return for funding and royalties.

For a firm to reach profitability requires time and money – typically ten or so years and several hundreds of millions of euros. This compares unfavourably with most other industry sectors. Few new drug candidates make it to market and, of those that do, many do not fully recoup investment. In this light, it is essential for both the biotechnology firm and the pharmaceutical company that their investment be recouped, not only in respect of the particular technology at hand, but also for the many failed projects.

The aim of the IP system is to induce innovation and subsequent commercialisation in view of these risks. Patent portfolios built around, for example, a gene sequence, generally cost in the order of millions of euros and are frequently the key business assets.

The licence granted by the biotechnology firm to the pharmaceutical company will invariably be exclusive for these reasons. As much of the patent life (of 20 years) has usually expired by the time the product is launched (potentially 10–12 years after filing), supplementary protection certificates were introduced on the basis of a similar rationale. In effect, these extend patent life for pharmaceutical products.

Businesses in more established fields of industry (eg 'white' goods) frequently only need to license when their technology is close to market or the product has been launched. Development time and cost are generally of a much lower order. Moreover, if the particular product is unsuccessful, the infrastructure of these businesses may support

commercialisation of other products, allowing costs to be amortised.

The biotechnology sector is highly regulated at virtually all stages of the product life cycle, including conduct of clinical trials and permitted pricing levels. The starting point in evaluating market shares for the purposes of the TTBE is to define the relevant market by reference to products that are substitutable. In biopharmaceutical markets, this concept is more difficult to apply. For example, several drugs may be available to treat a particular disease, but each of these could be targeted at a particular stage of therapy or therapy in a particular setting.

Importance of licensing in biotechnology industry

The Commission Guidelines recognise that licences may be granted in innovative markets but state that the Commission will, in analysing the effects of the licence, normally confine itself to examining the impact of the agreement on competition within existing product and technology markets.[4] Competition on such markets may be affected by agreements that delay the introduction of improved products or new products that over time will replace existing products. In such cases innovation is a source of potential competition that should be taken into account when assessing the impact of the agreement on product and technology markets. The Guidelines also recognise that in a limited number of cases it may be useful and necessary to define innovation markets. This would particularly be the case where the agreements affect innovation aimed at creating new products and where it is possible at an early stage to identify research and development poles. In such cases the parties must analyse whether after the agreement there will be a sufficient number of competing research and development poles left for effective competition in innovation to be maintained. Arguably, innovative drugs could prima facie have a 100 per cent market share so this could be key. For example, 'personalised medicine', potentially based on a patient's specific genetic make-up, will result in a 100 per cent position. Drugs brought to market under the **Orphan Medicinal Products Regulation, 2000**, will have the same result. Orphan drug status can be applied for regarding drugs developed to treat patients with a rare disease that would otherwise remain untreated, the principal incentive being market exclusivity. The Commission has not addressed the issue of the interface between the TTBE and orphan medicinal products and individual assessment may be required.

Commission guidelines

WILL BIOTECHNOLOGY LICENCES FIT WITHIN TTBE?

Certain elements must be present in any licence for it to fall within the TTBE's scope. In terms of IP rights covered, patents and know-how are included, but rights in biological materials (eg cell lines) and database rights are not. Licensing of research tools has also been expressly excluded but may be covered by the research and development block exemption.[5] Copyright in software is included for the first time.

The licence must be between two undertakings only and be for the production of goods or services incorporating or produced with the licensed technology.[6] If the agreement includes sub-licensing rights, this must not be the primary object of the agreement. Development licences may be covered.

MARKETS AND MARKET SHARES – LEGAL, COMMERCIAL AND ECONOMIC ISSUES

Competitors or non-competitors

It must first be determined whether the parties are competitors or non-competitors. This should be assessed from the position just before the parties entered into the licence agreement, provided that the agreement is not subsequently 'altered or amended in any material respect'.[7]

Competitors are defined in the TTBE[8]

as undertakings which compete on the relevant product market (actually and potentially) and/or technology market (actually only).[9] Companies compete on the relevant technology market if they license the relevant technology or substitutes for it. Undertakings compete on the relevant product market if they are both active on the product and geographical markets on which the contract products[10] are sold or which will be replaced by the contract products (actual competitors) or if they would, 'on realistic grounds', enter those markets in response to a small and permanent increase in prices[11] (potential competitors).

Market share tests

Different market share thresholds for competing and non-competing parties

Agreements between competitors will be exempted if they have a combined market share not exceeding 20 per cent of the relevant technology and product markets. For non-competitors, neither party's market share may exceed 30 per cent. Market shares of any licensees are to be added to that of the licensor when calculating the licensor's market share in order to take account of the presence of the licensed technology on the relevant product markets. These tests are likely to be difficult to apply in practice, particularly for innovative technologies and the new markets that they may create.[12]

Defining the relevant geographical and product markets[13] and determining market shares within them can be a difficult and time-consuming exercise, owing to the need to make complex judgment calls as to whether products are substitutes, the application of theoretical standards and the frequent lack of sufficient empirical data.

It is quite conceivable that in technology markets, a margin of error in the order of 10–20 per cent may arise. Such errors could affect whether or not the relevant agreement is exempted under the (first) safe harbour. There is a substantial risk of making an incorrect assessment. Keeping an audit trail of the reasoning behind any such assessment is therefore important.

Grace period

During the life of an agreement, the parties' market shares may oscillate between being under and over the thresholds. There is a two-year grace period during which agreements can still benefit from the TTBE following the year in which the threshold was first exceeded. Parties should consider monitoring the parties' market shares throughout the term of the agreement. If so, the licence itself could provide for who will undertake the assessment, who takes on the liability for correct reporting and the frequency of the assessment.

Example

In the case of a drug delivery technology, the possibilities of defining the market include defining it by reference to the mode of delivery (eg transdermal or oral) or to the nature of the treatments (eg diabetes or cancer) or even both. The onus is on the parties to carry out the individual assessment. However, if the agreement is later challenged, the court might reach a different opinion, relying on expert advice. Again, maintaining a file of the position agreed between the parties (or indeed involving economic competition law experts at the outset of the agreement) may be helpful.

'HARDCORE' RESTRICTIONS

The agreement must not contain 'hardcore' or 'excluded' restrictions

The parties must ensure that the agreement does not contain any 'hardcore' restrictions,[14] summarised in Table 1. Inclusion of any of these will result in the whole agreement falling outside the TTBE.

'EXCLUDED' RESTRICTIONS

The parties must also ensure that the agreement does not contain any 'excluded' restrictions:

Table 1: 'Hardcore' restrictions

Competitors
Price restrictions, including reciprocal running royalties where the licences are operated as a sham.
Output restrictions, excepting non-reciprocal agreements or where imposed on only one party in a reciprocal agreement.
Allocation of markets or customers, except (ie following will not disapply the TTBE):
- **technical field of use/product market** obligation on licensee (ie you may engage in field A; eg painkilling applications – for a new drug similar to aspirin);
- **technical field of use/product market** prohibition on either party (relating to field/market or exclusive territory reserved for other party) in non-reciprocal agreement (ie you must not engage in field B, eg cardiac treatment applications, for the same drug);
- granting exclusivity of territory to a licensee;
- restriction of **active and/or passive sales** (ie solicited and unsolicited sales respectively) into exclusive territory/customer group of other party in non-reciprocal agreement;
- restriction in non-reciprocal agreement of **active sales** by a licensee into another licensee's exclusive territory/customer group, provided other licensee was not a competitor of licensor at time of conclusion of its licence;
- own use restriction;
- restriction to produce goods only for a particular customer in non-reciprocal agreement, where the licence was granted to create an alternative source of supply for a customer.

Restrictions on licensee **exploiting** its own technology or on any of the parties carrying out **R&D**, except where necessary to prevent disclosure of know-how to third parties.

Non-competitors
Price restrictions, excluding (generally) imposition of a maximum price or recommended sale price.
Restrictions on **territory** into which, or **customers** to whom, licensee may passively sell products, except (ie following will not disapply the TTBE):
- into exclusive territory/customer group reserved for licensor;
- into exclusive territory/customer group of another licensee for the **first two years of sale** by the other licensee;
- own use or alternative sourcing restriction;
- restrictions on sales to end users by licensee operating as a wholesaler;
- restrictions on sales to unauthorised distributors by members of a selective distribution system.

Restrictions of active or passive sales to end users by a licensee which is a member of a selective distribution system at a retail level.

- Obligations on licensee to **license exclusively or assign-back** to licensor or the designated third party rights to any **severable improvements** licensee may make to licensed technology (ie those that can be exploited without using the licensed technology).

- Obligation on licensee **not to challenge validity of licensor's IPR** (although a licence termination right is exempt).

Agreements between competitors, viewed more strictly than those between non-competitors

Inclusion of any of these will result in the relevant restriction not being exempted. The remaining provisions of the agreement will still be valid, if the offending clause can be severed under national law.

KEY RESTRICTIONS – WHERE AGREEMENT IS WITHIN TTBE'S SCOPE

Agreements between competitors are viewed more strictly than those non-competitors. Regarding the former, agreements containing reciprocal licences are treated more severely than non-reciprocal agreements. This distinction is not relevant to the treatment of agreements between non-competitors.

'Exclusive' licensing (ie restrictions on production)

The Commission views 'exclusivity' as a reference to restrictions on production, not sales.[15] This is at odds with the ordinary usage of the term, but needs to be borne in mind when interpreting the Guidelines.

Hence, in an agreement between competing undertakings, a restriction on the licensor not to license others in the

licensee's territory is permissible, as is an obligation on one party not to produce in the other party's territory, except in the case of a reciprocal agreement between competitors.[16]

Sales restrictions

In the case of reciprocal agreements between competitors, sales restrictions on either party are not permitted.[17,18] However, regarding non-reciprocal agreements between competitors, restrictions on active and/or passive sales may be imposed on either party in respect of sales into the territory of the other party.[19] The licensee may also be restricted from actively selling into the exclusive territory of another licensee, provided that the other licensee was not a competitor of the licensor as at the date its licence was concluded.[20]

Best incentive – commission's approval of a period of absolute sales exclusivity

Regarding agreements between non-competitors, active sales restrictions on the licensee are permitted, as are passive sales restrictions on the licensee in favour of the licensor.[21] Passive sales restrictions on the licensee in favour of another licensee benefiting from an exclusive licence are permitted, provided that the restriction does not exceed two years.[22]

The two year total exclusivity period starts on the date of product launch by that other licensee rather than on the date of first licence signature as was the position under the old TTBE. This provided for a five year total exclusivity period. Biotechnology firms are likely to need total exclusivity for much longer than two years to recoup their investment, according to lobbyists.

NON-ASSERTION AND SETTLEMENT AGREEMENTS

TTBE allows in principle for non-assertion and settlement agreements

Support in principle for these types of agreement is given in the new TTBE.[23] Non-challenge clauses included in settlement and non-assertion agreements and that would not be covered by the TTBE are generally considered to fall outside Article 81(1) as the very purpose of the agreement is to settle existing disputes and/or avoid future disputes.

INDIVIDUAL ASSESSMENT – POSSIBLE ARGUMENTS

The Guidelines provide a general framework for analysis of agreements falling outside the block exemption, including factors to take into account when assessing technology pools under Article 81(1) which are not covered by the TTBE. There is welcome recognition that agreements to which a research institute is a party are unlikely to be caught by Article 81(1), as such research institutes lack the production and distribution assets to launch products.[24]

The Commission has acknowledged the pro-competitive nature of licensing in both the TTBE and Guidelines[25] and accepts the need for substantial investment to develop technology, to induce and recoup investment and for Article 81(1) to be applied in this light. However, the best incentive would be the Commission's blessing to a period of absolute sales exclusivity of sufficient length to increase the likelihood of investment being recouped. The two year period regarding passive sales restrictions in agreements between non-competitors is likely to be too short. Moreover, the Commission states that outside the TTBE the Article 81(3) criteria are unlikely to be met if the period is longer than two years. Although the statement does not rule out arguments for longer periods in light of the special characteristics of the biotechnology sector, it places the onus firmly on the parties to justify this.

CONCLUSION

These issues affect both licensors and licensees. Licensors often need various restrictions to protect their IP and maximise the value of their technology. During the consultation period on the draft TTBE considerable reservations were expressed by those in industry, etc, that the new rules might act to curtail investment in new technology or reduce routes to market and result in increased

management and external professional costs for the sector. However, many of these concerns were addressed in the final version of the block exemption. While for those licences where the parties do not clearly fall below the market share thresholds an extra compliance burden is involved, it is important to bear in mind that falling outside the TTBE does not automatically give rise to a breach of Article 81(1). If an agreement is drafted with the TTBE and the Guidelines in mind, this will reduce the likelihood of breach of Article 81 arising.

Falling outside the TTBE may be costly for industry

However, it may also be costly for industry to ignore these rules, both in terms of the financial and legal consequences already mentioned for industry and also the hidden costs associated with delays in negotiating licence deals, carrying out 'due diligence' exercises when seeking to acquire biotechnology firms and managing disputes, eg settling patent litigation.

PRACTICAL POINTS

The suggested approach for tackling EU competition law issues arising from technology licences is as follows:

- Make full use of the Notice on Agreements of Minor Importance.[26]
- Assess whether the parties are competitors or not.
- Assess if the relevant market share thresholds exceeded.
- Consider if any other relevant block exemptions apply such as that for vertical agreements, research and development, and specialisation.
- If yes, look to the independently controlled technologies concept and, if this does not apply, then assess the agreement under Article 81.
- If not, does the proposed agreement contain any 'hardcore' or 'excluded' restrictions?

All existing licences – entered into before or after 1st May, 2004 – will also need to be reviewed and possibly renegotiated to ensure compliance by the end of the transitional period, ie 31st March, 2006.[27] Agreements can benefit from the safe harbour provided by the block exemption for as long as the IPR for the licensed technology have not expired or become invalid, or in the case of know-how remains secret.

Companies will need to adjust their EU competition law auditing and compliance programmes to address this area as well, taking into account relevant legal, commercial and economic issues.

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References and notes

1. 772/2004 and OJ 20004/C 101/02.
2. 240/96.
3. These must be substitutable for the licensed technology at a comparable cost to the user: Guidelines, paragraph 131.
4. Para. 25, Guidelines.
5. Regulation 2659/2000 on the application of Article 81(3) of the Treaty to categories of research and development agreements.
6. Articles 1(b) and 2 of TTBE.
7. TTBE, Article 4(3); Guidelines, paragraphs 31 and 68.
8. Article 1 of the TTBE.
9. The activities of connected undertakings need to be taken into account as well: TTBE, Article 1(2).
10. This term is defined to include both products and services; Articles 1(e) and 1(f) of the TTBE.
11. A concept that also features in the US Antitrust Guidelines for the Licensing of Intellectual Property.
12. The TTBE states that where a new technology has not yet generated any sales, it will be considered to have a zero market share, with the market share accumulating as sales commence (Guidelines, paragraph 70).

However, if the technology is innovative, the market share may quickly exceed the relevant threshold, leaving its owner facing individual assessment. However, reference will also need to be made to any substitutable products.

13. If the licence agreement concerns two separate product markets or two separate geographic markets, the TTBE may apply to one of the markets and not to the other (Guidelines, paragraph 69).
14. To be hardcore, a restriction must be unambiguously anti-competitive by reference to its object alone: Guidelines, paragraph 14.
15. Guidelines, paragraph 162.
16. TTBE, Articles (4)(c)(ii) and (iii).
17. Article 4(1)(c), (iv) and (v) of the TTBE.
18. Guidelines, paragraph 96.
19. TTBE, Article 4(1)(c)(iv).
20. TTBE, Article 4(1)(c)(v).
21. TTBE, Article 4(2)(b)(i).
22. TTBE, Article 4(2)(b)(ii).
23. Guidelines, paragraphs 17, 43, 148 and 209.
24. Guidelines, paragraph 164.
25. TTBE, recitals (5) and (6); Guidelines, paragraphs 8 and 17.
26. OJ 2001 C.
27. TBE, Article 10.