Innovation competition, economic dependence and exceptional remedies: three interesting aspects of the EC's decision in Johnson & Johnson/Actelion

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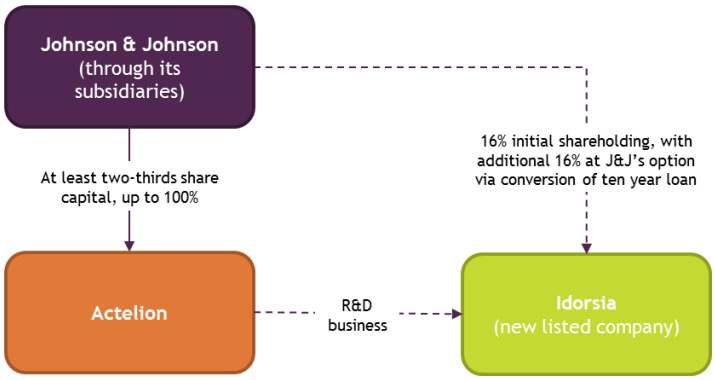
On 9 June 2017 the European Commission cleared Johnson & Johnson's USD 30 billion takeover of Swiss biopharmaceutical company Actelion, subject to conditions. This briefing note considers three interesting aspects of the Commission's decision (published on 23 August 2017): (1) the Commission's theory of harm relating to two pipeline compounds in phase 2 clinical trials, (2) the Commission's finding that J&J would have the ability to influence the development of one of the overlapping compounds on the basis of Idorsia's economic dependence, and (3) the J&J commitments accepted by the Commission in return for Phase I clearance under the EU Merger Regulation.

Background

Johnson & Johnson (J&J) announced its offer to acquire Actelion in January 2017. As part of the transaction and prior to completion, Actelion would demerge its R&D operations into a new company, Idorsia, to be listed on the SIX Swiss Exchange (Demerger). J&J would take an initial shareholding of 16% in Idorsia, with an option to increase its shareholding by a further 16% via a convertible loan.



The Commission's analysis - overlaps in pipeline insomnia treatments

The Commission identified an overlap between two compounds under development by each of Actelion and J&J for the treatment of insomnia (ACT-541468 and JNJ-7922). ACT-541468 was to transfer to Idorsia through the Demerger and JNJ-7922 was being co-developed by J&J with Minerva Neurosciences (in whom J&J held an equity stake). Minerva had the rights to market JNJ-7922 (if successful) in the EEA. The compounds were both in phase 2 of clinical testing and are two of three orexin receptor antagonists currently in phase 2 or 3 with an intended launch in the EEA.[1] No orexin receptor antagonists currently have marketing approval in the EEA.

[1] Pharmaceutical compounds undergo different phases of clinical testing during their development: Phase 1 marks the start of clinical testing on humans, around 8-10 years before the product is marketed (with a generally acknowledged success rate of no more than 10%), Phase 2 involves working out the proper dosage for the patients and defining the areas of application, around 4-5 years before the product is marketed (success rate of approximately 30%) and Phase 3 involves establishing the product's effectiveness on larger groups of patients, around 3 years before the product is marketed (success rate of under 50%): see case M.2312 - *Abbott/BASF* - decision of 28 February 2001, para 18.

The Commission's market investigation indicated that orexin receptor antagonists, if successfully brought to market, could constitute a significant improvement over existing standards of care for insomnia. This led the Commission to conclude that orexin-antagonists would be a distinct product market.

The Commission's theory of harm was that J&J would have the ability and incentive to delay, discontinue or "reorient" the development of ACT-541468 or JNJ-7922. The Commission considered that reorientation may involve targeting specific therapeutic indications or patient groups within insomnia so that the two compounds would not directly compete with each other if brought to market.

Commitments

The Commission accepted commitments from J&J in respect of both ACT-541468 and JNJ-7922 in return for clearance at Phase I.

J&J's ACT-541468 commitments were to:

i. Limit its shareholding in Idorsia to a maximum of 9.9%, or 16% if another party (not named in the decision) increased their share to at least 20%;

ii. Not obtain any information regarding ACT-541468 from Idorsia; and

iii. Waive any right to nominate any board members of Idorsia.

J&J's JNJ-7922 commitments were to:

i. Divest its minority shareholding in Minerva;

ii. Grant Minerva final say on all decisions concerning the global development of JNJ-7922 for insomnia;

iii. Waive its royalty rights on Minerva's sales in the EEA;

iv. Continue to fund a certain percentage of development costs of JNJ-7922 for insomnia; and

v. Continue supporting Minerva in relation to JNJ-7922.

Comment

Phase 2 pipeline compounds and the "reorientation" theory of harm

This case is thought to be only the second example of the Commission examining overlaps between pipeline pharmaceutical products which are yet to reach phase 3 clinical trials. In a 2015 decision regarding a joint venture between Novartis and GlaxoSmithKline (GSK), the Commission considered overlapping phase 2 compounds under development in oncology, which were being acquired by Novartis as part of the wider transaction.[2] In *Novartis/GSK Oncology Business*, the Commission found that the transaction would reduce Novartis' incentives to continue investing in some of the phase 2 compounds, thereby reducing competition in innovation. However, the significance of this case is that J&J would have held only limited interests in both compounds in the EEA, owing to the size of J&J's initial shareholding in Idorsia (16%) and Minerva holding the rights to market JNJ-7922 in the EEA. Notwithstanding this, the Commission seems to have analysed the overlap in the same way as if it were a 100% acquisition, as in *Novartis/GSK Oncology Business*. Taken together, these cases may reflect a trend of increased scrutiny of pipeline innovation, and underline that the Commission is not deterred by the low probability of success of compounds in phase 2 trials.

[2] See case M.7275 *Novartis/GlaxoSmithKline Oncology Business* – decision of 28 January 2015.

Going forward, it would therefore be sensible for parties to assess whether there are any overlaps in their entire pipeline portfolios, regardless of the stage of development or the size and nature of the parties' interest in them. This will be especially relevant to transactions involving potentially innovative products.

This case is also thought to be the first time the Commission has explicitly considered possible *reorientation* of pipeline compounds as part of its theory of harm in a merger case, in addition to discontinuance and delay.[3] The Commission explained that "reorientation" may involve, for example, targeting specific therapeutic indications or patient groups in order to prevent the two pipeline products from directly competing with each other. Defending a reorientation theory of harm may place a difficult evidentiary burden on parties, particularly as, by definition, phase 2 pipeline compounds are at a very early stage of development.

J&J's ability to discontinue, delay or reorient ACT-541468

The Commission found that J&J would have been able to exercise de facto influence over the strategic decisions of Idorsia regarding ACT-541468, owing to the economic, IP and structural links between the parties (including J&J's potential 32% shareholding in Idorsia). The Commission referred to paragraph 20 of the Consolidated Jurisdictional Notice, which contemplates that in exceptional circumstances, situations of economic dependence may give rise to decisive influence and de facto control.[4]

In reaching this conclusion it is notable that:

i. The Commission assessed J&J's shareholding on the basis of its potential rather than its *initial* shareholding at the time of the transaction. Whilst there is precedent for this approach,[5] in that case the parties' stated intention was that the option to convert a loan into a 50% shareholding would be exercised shortly after completion, and the transaction structure was only chosen for accounting and re-organisation purposes.

ii. Even at 32%, J&J's shareholding is at the lower end of the spectrum compared to the Commission's previous findings of *de facto* influence via economic dependence. Although there have been examples involving shareholdings as low as 30%,[6] most of the precedents fall in the 40-50% category.[7] Furthermore, cases at the lower end of the spectrum have involved actual shareholdings, as opposed to options to take additional shares.

iii. The Commission found that as an R&D company Idorsia would strongly depend on J&J for financing – by virtue of a CHF 580m loan and a CHF 250m credit facility – and IP rights – by virtue of a cross-licence. This was despite precedents where financing arrangements had not given risen to *de facto* influence, for example in *Lockheed Martin* where one party had agreed to guarantee USD 250m worth of debt (the guarantor also held a 20% shareholding in the guarantee's parent company).[8] It is also notable that the Commission cited the vanilla IP cross-licensing arrangement as one of the reasons for Idorsia's dependence on J&J.

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[3] In *Novartis/GSK Oncology Business*, the Commission's theory of harm (as regards the phase 2 pipeline products) was based on the possible *discontinuance* of, or *significant reduction of current R&D efforts* in, certain competing clinical research programs, without expressly mentioning possible reorientation. The Commission did refer to the differentiation of pipeline products, but in the context of concluding that Novartis would have reduced incentives post-transaction to pursue and differentiate two of the clinical research programs. It considered that these research programs would likely be deprioritised, resulting in either their abandonment or a significant reduction in R&D efforts. See case M.7275 *Novartis/GSK Oncology Business* - paras 105-106.

[4] Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings, OJ C 95/1, 16 April 2008.

[5] See case M.625 *Nordic Capital/Transpool* – decision of 23 August 1995.

[6] See case ECSC.1031 *US/Sollac/BAMESA* – decision of 28 July 1993.

[7] See case M.794 *Coca-Cola/Amalgamated Beverages* – decision of 22 January 1997.

[8] See case M.697 *Lockheed Martin/Local Corporation* – decision of 27 March 1996.

It remains to be seen whether the Commission will adopt this arguably broader approach to control on the basis of economic dependence in cases outside the pharmaceutical/innovation competition context.

The remedy: no requirement to divest

Finally, it is worth noting that the Commission normally expects Phase I commitments to be "clear-cut" remedies that sufficiently rule out its "serious doubts" about the transaction and the theories of harm. This means that the default position in this context is normally divestment – either of an overlapping product or shareholding in a competitor where that gives rise to the concern.[9] In this case, however, the Commission allowed J&J to retain an interest (albeit reduced) in both compounds. The Commission described the remedy as involving "structural measures" to ensure J&J would not be able to influence either compound.[10] This should provide some comfort to parties facing similar overlaps, as the Commission has demonstrated that there is scope for flexibility in agreeing a suitable remedy.

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[9] See Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and Commission Regulation (EC) No 802/2004, paras 17-18 and 58. This is also specifically stated in the decision at para 81.

[10] In this way the remedy appears to be an example of the exceptional circumstances mentioned in para 59 of the Commission Notice on remedies.