Merger control in the pharma sector

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A DIVISION OF THE I.C.C.
COMMERCIAL CRIME SERVICES BRANCH

ΠΕΡΙΕΧΟΜΕΝΑ

Διοργάνωση: ΝΟΜΙΚΗ ΒΙΒΛΙΟΘΗΚΗ eco.nomia
Υπό την αιγίδα: Ελληνική Επιτροπή Ανταγωνισμού
Υπό τη θεσμική υποστήριξη: ΣΕΒ

I. Ιδιαιτερότητες & Χαρακτηριστικά του Κλάδου της Φαρμακοβιομηχανίας

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- Ο ανταγωνισμός στον κλάδο της φαρμακοβιομηχανίας επηρεάζεται από ιδιαίτερους παράγοντες όπως:

  - Προστασία δικαιωμάτων πνευματικής ιδιοκτησίας
  - Συνεχής έρευνα για τη δημιουργία νέων καινοτόμων προϊόντων (R&D)
  - Ανάγκη πρόσβασης σε κεφάλαια από μικρότερες επιχειρήσεις
  - Κύκλος ζωής ενός φαρμακευτικού προϊόντος
  - Άδεια κυκλοφορίας προϊόντων
  - Νομοθετικός καθορισμός τιμών

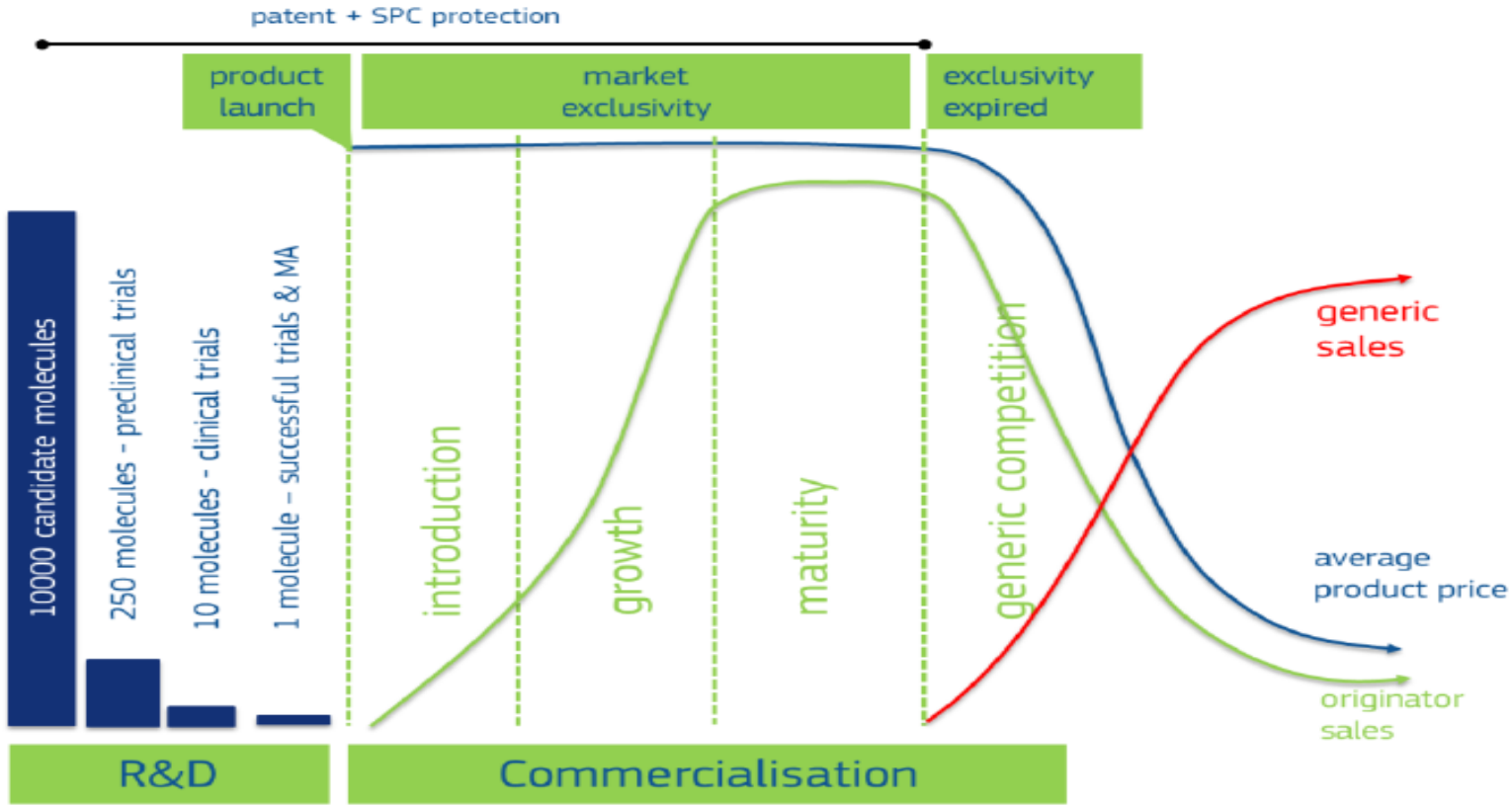
I. Ιδιαιτερότητες & Χαρακτηριστικά του Κλάδου της Φαρμακοβιομηχανίας

- **Κύκλος Ζωής** ενός φαρμακευτικού προϊόντος

  - Ανταγωνισμός για καινοτομία και εφεύρεση
  - ↓
  - Δημιουργία νέου προϊόντος
  - ↓
  - Δικαίωμα αποκλειστικής εκμετάλλευσης για περιορισμένο χρονικό διάστημα
  - ↓
  - Απώλεια προστασίας και ανταγωνιστική πίεση από γενόσημα φάρμακα

- **Η θεωρία βλάβης (theory of harm) που ανακύπτει και εξετάζεται διαφέρει ανάλογα με το στάδιο του κύκλου ζωής στο οποίο βρίσκεται το υπό εξέταση προϊόν.**

Figure 5: Pharmaceutical product life-cycle



I. Ιδιαιτερότητες & Χαρακτηριστικά του Κλάδου της Φαρμακοβιομηχανίας

- ***Το εθνικό νομοθετικό και κανονιστικό πλαίσιο:*** Η επίδραση κανόνων τιμολόγησης

  - *TEVA/RATIOPHARM (M.5865)*

  (62) As similarly noted in previous decisions, for the purposes of assessing competition in pharmaceutical markets it is also necessary to bear in mind that such markets may display certain rigidities as regards both pricing and entry.

  *(67) It follows that, **at moderate concentration levels**, the existence of pricing constraints is one factor allowing the Commission to conclude that smaller competitors may act as a **sufficient constraining influence**. Such a consideration supports the conclusion of no serious doubts in a number of places in this Decision, and in particular in the cases dealt with at recital 386 below.*

  *(68) Nonetheless, **at very high concentration levels** for a particular product and/or in the presence of additional features of the market structure, the relevance of pricing regulations and tendering as a sufficient competitive constraint cannot, on the basis of the market investigation, be concluded with confidence. Thus, many respondents to the market investigation, when they did believe that price increases for prescription medicines were possible, specifically cited the eventuality of very high market shares at product level in support of this possibility. It should also be noted that, if authorities or insurers are unable to constrain prices, at doctor and patient level there is likely, for all but more routine medications, to be an **absence of price sensitivity** due in particular to the fact that patients do not directly bear the costs.*

  *(69) Finally, it should in any case be borne in mind that the existence of a **price ceiling** does not exclude that the relevant counterfactual in the absence of the merger would have been continuing price decreases. Many national markets have, indeed, shown very significant decreases in the prices of common generic medicines over recent years, a trend which relies on sufficient competition in the market. The Commission in its assessment has therefore relied also on the basic economics of generic competition, namely, for unbranded generics, the fact that the goods involved are non-differentiated (and therefore competitors compete on price).*

I. Ιδιαιτερότητες & Χαρακτηριστικά του Κλάδου της Φαρμακοβιομηχανίας

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- Ποικιλομορφία των επιχειρήσεων που συμμετέχουν σε συγκεντρώσεις στον κλάδο της φαρμακοβιομηχανίας:
  - Κατασκευαστές πρωτότυπων φαρμάκων («καινοτόμοι», «δημιουργοί») (“*originators*”)
    [SHIRE /BAXALTA (Case M.7951)]
  - Κατασκευαστές γενόσημων φαρμάκων (“*generics*”)
    [TEVA_ALLERGAN GENERICS (M.7746)]
  - Κατασκευαστές βιοομοειδών (“*biosimilars*”)
    [PFIZER/ HOSPIRA (M.7559/2015)]
  - Χονδρέμποροι και διανομείς
    [McKesson/UDG Healthcare (Case M.7818)]
  - Λιανοπωλητές (φαρμακεία)
    [Celesio/ Sainsbury's UK pharmacy business (Case M.7721)]
  - Παγκόσμιες επενδυτικές τράπεζες
    [GOLDMAN SACHS/ASTORG ASSET MANAGEMENT/HRA PHARMA (Case M.7887)]

II. Η ΕΝΝΟΙΑ ΤΗΣ ΣΥΓΚΕΝΤΡΩΣΗΣ: *(Α) ΜΕΣΑ ΕΛΕΓΧΟΥ*

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- Συγκέντρωση επιχειρήσεων πραγματοποιείται όταν προκύπτει μόνιμη μεταβολή του ελέγχου. Η έννοια του ελέγχου ορίζεται ως δυνατότητα καθοριστικού επηρεασμού της δραστηριότητας μιας επιχείρησης η οποία μπορεί να απορρέει από δικαιώματα, συμβάσεις ή άλλα μέσα, είτε μεμονωμένα είτε σε συνδυασμό, και λαμβάνοντας υπόψη τις σχετικές πραγματικές ή νομικές συνθήκες.

- Έλεγχος μπορεί να αποκτηθεί με οποιοδήποτε μέσο:

  - Καθαρά **οικονομικοί δεσμοί** μπορεί να διαδραματίσουν αποφασιστικό ρόλο για την απόκτηση του ελέγχου. Σε εξαιρετικές περιπτώσεις, μια **κατάσταση οικονομικής εξάρτησης** μπορεί να οδηγήσει σε **έλεγχο de facto**, εφόσον, για παράδειγμα, πολύ σημαντικές μακροπρόθεσμες συμφωνίες εφοδιασμού ή παροχής πιστώσεων με προμηθευτές ή πελάτες, σε συνδυασμό με διαρθρωτικούς δεσμούς, εξασφαλίζουν αποφασιστική επιρροή.

II. Η ΕΝΝΟΙΑ ΤΗΣ ΣΥΓΚΕΝΤΡΩΣΗΣ:
(Α) ΜΕΣΑ ΕΛΕΓΧΟΥ (De Facto Έλεγχος)

- *J&J / ACTELION (M.8401)*

*(46) "In this case, there will be **strong economic links** between J&J and Idorsia on a long-term basis. As an R&D company, Idorsia's activities strongly depend on financing and IP rights. In that respect, J&J will provide to Idorsia a 10-year loan of approximately EUR 542 million, as well as a 15-year credit facility of approximately EUR 234 million. J&J will also provide Idorsia access to IP rights […] through the cross licensing arrangement. These economic links will be coupled with a **structural link**, with J&J acquiring between 16% and 32% of Idorsia's share capital while all the other shareholders will each hold less than 5% of the shares. J&J will also appoint one or two board member(s) if it decides to convert its loan to hold more than 20% shares. Therefore, there will be strong economic and structural links between J&J and Idorsia on a lasting basis.*

*(48) In view of the above, J&J is likely to have the ability to **de facto influence strategic decisions** on the development of Actelion's pipeline ACT-541468, which represents one among the 11 pipeline programs in Idorsia's portfolio."*

II. Η ΕΝΝΟΙΑ ΤΗΣ ΣΥΓΚΕΝΤΡΩΣΗΣ: *(Β) ΑΝΤΙΚΕΙΜΕΝΟ ΕΛΕΓΧΟΥ*

- Η απόκτηση ελέγχου **επί των στοιχείων ενεργητικού** μπορεί να θεωρηθεί συγκέντρωση **μόνον εάν** τα στοιχεία αυτά αποτελούν το σύνολο ή τμήμα μιας επιχείρησης, δηλαδή μια επιχειρηματική δραστηριότητα με παρουσία στην αγορά, της οποίας μπορεί να **προσδιορισθεί σαφώς ο κύκλος εργασιών.**

- Η πράξη που περιορίζεται σε **άυλα στοιχεία του ενεργητικού**, όπως σήματα, διπλώματα ευρεσιτεχνίας ή δικαιώματα πνευματικής ιδιοκτησίας, μπορεί επίσης να θεωρηθεί ότι αποτελεί συγκέντρωση, εάν τα στοιχεία αυτά συνιστούν επιχειρηματική δραστηριότητα **με κύκλο εργασιών στην αγορά**.

(βλ. Κωδικοποιημένη ανακοίνωση της Επιτροπής για θέματα δικαιοδοσίας)

II. Η ΕΝΝΟΙΑ ΤΗΣ ΣΥΓΚΕΝΤΡΩΣΗΣ: *(Β) ΑΝΤΙΚΕΙΜΕΝΟ ΕΛΕΓΧΟΥ*

- **ΟΜΩΣ**: Συνιστά συγκέντρωση και η απόκτηση στοιχείων που **αναμένεται σε εύλογο χρονικό διάστημα** να επιφέρουν κύκλο εργασιών στην αγορά

- *Novartis/ GlaxoSmithKline (M.7872)*

*(7) "The Target business is composed of the **rights** to develop, manufacture, promote and market ofatumumab for auto-immune indications, and **tangible assets**, such as biological materials and cells, product inventory, Investigational New Drug Applications granted by the US Food and Drug Administration, clinical trial data, as well as **supply contracts**.*

*(10) Moreover, Novartis has agreed to pay to GSK **royalties of up to 12% on any future net sales** of ofatumumab for auto-immune indications. This fact suggests that both Novartis and GSK expect that the timely entry of ofatumumab in the market for auto-immune indications is quite likely, including in particular the pemphigus vulgaris indication for which the drug is already in the advanced Phase III trials. Likewise, the fact that Novartis has agreed to **pay to GSK US$ 200 million following the start of phase III study** in the use of ofatumumab for multiple sclerosis, on top of the US$ 300 million payable at closing, suggests that both undertakings expect that the start of these phase III trials is quite likely and imminent. This is an additional factor supporting the conclusion that the business acquired by Novartis is reasonably expected to enter the market within a reasonable period of time*

*(11) The Commission therefore considers that the acquisition of the ofatumumab assets in question falls within the scope of the Merger Regulation because it involves the acquisition of the intangible and all core tangible assets that are **expected to enable the acquirer to access the market, and therefore to produce a market turnover, within a reasonable timeframe**. Indeed, in the context of this kind of industries with important research and development projects, the acquisition of assets that are already in phase III clinical trials can be reasonably assumed to be capable of generating a turnover in the foreseeable future."*

III. ΑΡΜΟΔΙΟΤΗΤΑ & ΠΑΡΑΠΟΜΠΗ

- <u>Παραπομπή στην Ευρ. Επιτροπή βάσει Άρθρου 22(1) Κανονισμού Συγκεντρώσεων:</u>

  Διεύρυνση του πεδίου εφαρμογής του θεσμού της παραπομπής και σε άλλες περιπτώσεις εκτός από digital και "killer" acquisitions, όπως π.χ. όταν αφορά επιχειρήσεις με σημαντική δραστηριότητα στην καινοτομία

  <u>Προθεσμία υποβολής αιτήματος παραπομπής</u>: 15 εργάσιμες ημέρες από την ημερομηνία που «έγινε γνωστή» στο οικείο κράτος μέλος η συγκέντρωση (όριο 6 μηνών;) → Ανασφάλεια Δικαίου

- *<u>Illumina/GRAIL (M.10188)</u>:* Vertical (re)merger

  Στις 9 Μαρτίου 2021, η Γαλλική Αρχή Ανταγωνισμού ζήτησε από την Ευρ. Επιτροπή να εξετάσει την συγκέντρωση σύμφωνα με το άρθρο 22 του Κανονισμού για τις συγκεντρώσεις και εν συνεχεία υπέβαλαν αντίστοιχο αίτημα οι Αρχές Ανταγωνισμού της Ολλανδίας, του Βελγίου, της Ελλάδας, της Ισλανδίας και της Νορβηγίας.

  Η Ευρ. Επιτροπή δέχτηκε το αίτημα καίτοι οι κύκλοι εργασιών δεν ξεπερνούσαν τα εφαρμοζόμενα όρια.

  <u>Έλεγχος για Gun Jumping</u>: Η συγκέντρωση ολοκληρώθηκε ενώ η εξέταση βρίσκεται σε Phase II στάδιο.

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ: *(A1) Προϊοντική (FDP)*

BALLAS PELECANOS & ASSOCIATES L.P.C.

A1. Finished dose pharmaceutical products *(FDP)*

1.1. Κριτήρια Διάκρισης Φαρμάκων:

- **Ανατομικό-Θεραπευτικό-Χημικό Σύστημα Ταξινόμησης (ATC Level - EphMRA)**

Teva/PGT OTC Assets (M.8889)

*"(18) The ATC system is a hierarchical and coded four-level system which classifies medicinal products by class according to their indication, therapeutic use, composition, and mode of action. ……Medicinal products are classified according to the ATC system in the **IMS Midas data base**."*

- **ATC 1:** medicinal products are divided into the 16 anatomical main groups
- **ATC 2:** refers to a pharmacological or therapeutic main group (the main disease groups that the medicine intends to address)
- **ATC 3:** groups medicinal products by their specific therapeutic indications (the different drug actions that will address the disease in question)
- **ATC 4:** the most detailed one (not available for all ATC 3) and refers for instance to the mode of action (e.g. distinction of some ATC 3 classes into topical and systemic depending on their way of action) or any other subdivision of the group)

- **Μοριακή/Χημική Σύσταση (Molecule Level)**

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ:
(A1) Προϊοντική (FDP)

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➢ Γαληνική Μορφή (Galenic Form)

- *Teva/PGT OTC Assets (M.8889)*

*(26) "…medicines are differentiated not only by their active ingredient(s) but also, in particular, as recognized by the European regulatory framework for medicines for human use, by their **posology (or dosage), pharmaceutical form, method and route of administration** (**collectively referred to as "galenic form"** in this decision) which may limit their substitutability. The galenic form of a medicine may in some cases influence the preferences of consumers or be targeted to specific patients groups (e.g. children), and therefore, two medicines with the same active ingredient and indications may not be (fully) interchangeable for certain patient groups. Certain medicines can also be indicated only for a specific patient group (e.g. adults, children or babies), meaning that they have only been shown to be safe and effective when administered to that specific group of patients."*

➢ Ελευθέρως Διανεμόμενα – Συνταγογραφούμενα (OTC – Rx)

- *Teva/PGT OTC Assets (M.8889)*

(22) "The Commission has in the past defined separate markets for medicines which can be dispensed only against a prescription and those which can be sold OTC. Medical indications, side effects, regulatory framework, distribution and marketing tend to differ between these drug categories, even if the active ingredients may sometimes be identical.

(25) However, in certain cases, products which are available OTC can still be reimbursable if bought on prescription. Furthermore, it cannot be excluded that OTC and prescription products compete with each other, especially in cases where the status of the drug is not clearly limited to either OTC or prescription"

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ:
(A1) Προϊοντική (FDP)

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1.2. Επιλογή Επιπέδου Ταξινόμησης:

- Το επίπεδο ταξινόμησης βάσει του οποίου οριοθετείται η σχετική αγορά διαφέρει ανά περίπτωση ανάλογα με το εάν η συγκέντρωση αφορά φάρμακα πρωτότυπα ("originators") ή γενόσημα ("generics")

(α) Originators → ATC 3 ως σημείο εκκίνησης της ανάλυσης

- *Teva/PGT OTC Assets (M.8889)*

  *"(19) The Commission has referred to the third level **(ATC 3) as the starting point** for defining the relevant product market. However, in a number of cases, the Commission found that the ATC 3 level classification did not yield the appropriate market definition within the meaning of the Commission Notice on the Definition of the Relevant Market. In particular in relation to originator and generic medicines, the Commission has considered in previous decision plausible product markets at **the ATC4 level**, at a **level of a molecule** or a **group of molecules** that are considered interchangeable so as to exercise competitive pressure on one another. However, it should be borne in mind that the overlap in therapeutic uses does not necessarily imply any particular economic substitution patterns between products.*

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ: *(A1) Προϊοντική (FDP)*

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(β) Generics → Molecule level ως σημείο εκκίνησης της ανάλυσης

- *TEVA/ RATIOPHARM (M.5865)*

*(12) "However, in recent cases involving generic companies the Commission, based on its market investigation, has tended to identify competition issues – where such issues arose – more often at the **molecule level**, at the **ATC4 level**, or on the basis of a **group of molecules**. This is because generic pharmaceutical companies typically produce copies of originator drugs which therefore can normally be viewed as the closest substitute to those drugs."*

*(13) "For all those products which were specifically investigated in the market investigation, the ATC3 level rarely appeared to be the correct range of products for analyzing competition. In the genericised pharmaceutical markets concerned by the notified transaction, the Parties achieved significant market shares, in a large majority of cases, only when such markets were looked at at the molecule level. In most cases, responses to the market investigation, whether from competitors, customers, insurers or national authorities, indicated that **demand for medicinal products based on established and well-known pharmaceutical molecules is specific to the molecule in question** (and its galenic form, see below), at least for prescription products and products for hospital use. The Parties compete, principally, for sales of products based on the originator molecule (i.e. the product which was first to market and benefited from patent protection which has now expired, as well as an originator brand name), and only to a limited extent against products based on other molecules."*

*(14) "In a certain number of cases, however, a **group of molecules** can be considered interchangeable for a wide range of applications and the relevant market in this case should be defined on the basis of all molecules which are so interchangeable. Such a definition may in principle coincide with the ATC3 or even a higher level, but more commonly it is not wider than ATC4 and may be confined to a **subset of molecules within the ATC4 class**."*

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ:
(A1) Προϊοντική (FDP)

BALLAS PELECANOS & ASSOCIATES L.P.C.

1.3. Διάκριση μεταξύ "Originators" και "Generics"

Σε γενικές γραμμές, υπάρχουν δύο τύποι φαρμακευτικών προϊόντων που στοχεύουν να προσφέρουν εναλλακτικές λύσεις σε σχέση με τα πρωτότυπα φάρμακα (originators):

(α) συνθετικά γενόσημα μικρών μορίων (synthetic small-molecule generics) και

(β) βιοομοειδή προϊόντα (biosimilars)

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ:
(A1) Προϊοντική (FDP)

BALLAS PELECANOS & ASSOCIATES L.P.C.

(α) Τα συνθετικά γενόσημα μικρών μορίων (synthetic small-molecule generics) → Ενιαία σχετική αγορά που περιλαμβάνει και τα πρωτότυπα

- *CVC / TEVA'S WOMEN'S HEALTH BUSINESS (M.8675)*

(14)*"A potential distinction between generic and proprietary medicines was considered by the Commission. For example, in a previous case the Commission made a distinction between originator and generic medicinal products stating that there is a separate market for the wholesale of generic medicines as compared to the wholesale of proprietary medicines. In other cases, however, the Commission set out that* ***where the market is genericised, originator drugs and generics could be considered to be close substitutes for a given indication and a product market may be defined as including both the generic and the proprietary medicine****."*

- *PFIZER/HOSPIRA (M.7559)*

(33) *"Small-molecule originator products and generic products based on the same active principle can generally be considered* ***homogeneous products*** *that compete mainly on price, especially in the case of hospital drugs procured through competitive tenders. While manufacturers, especially originators, may try to differentiate their product as a strategy to soften the intensity of price competition, measures have been taken in European countries to constrain their ability to do so. Such measures include for example incentives for physicians to write generic prescriptions (i.e. financial incentives based on targets of generic prescriptions), generic substitution by the pharmacist regardless of the brand name used by the prescriber, incentives for pharmacists to dispense the cheapest available versions of a given medicine (e.g. regressive margins, obligation to stock and dispense the cheapest generic), and incentives for patients to ask for the cheapest available versions of their medicines (i.e. differentiated patient co-payments based on relative prices). These measures are designed to encourage generic uptake by making prescribers, pharmacists and patients more sensitive to price differences. Evidence shows that they can be effective at fostering price competition."*

- *MYLAN/ ABBOTT EPD-DMPFIZER/HOSPIRA (M.7379)*

(16) *"Therefore, in line with the precedents, the Commission considers that* ***in relation to the overlapping molecules the product market includes both generic and originator versions****."*

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ: *(A1) Προϊοντική (FDP)*

BALLAS PELECANOS & ASSOCIATES L.P.C.

(β) Τα Βιοομοειδή (Biosimilars) → Διακριτή, αυτοτελής σχετική αγορά

- *PFIZER/HOSPIRA (M.7559)*

*(34) "Biological products are intrinsically differentiated due to their complex molecular structure. As discussed above, **no biosimilar product is identical either to the original biologic product on which it is based, or to any other biosimilar product**. Despite their similarity stemming from pre-clinical bioequivalence studies, regulatory authorities consider their differences sufficiently significant to request clinical trials to prove the clinical equivalence between every new biosimilar and the original biologic product on which it is based, for at least one major indication. In particular, the EMA establishes for every family of biological medicines a specific set of clinical evidence required for the regulatory approval of new biosimilars. As a consequence, not only the regulatory approval and the clinical evidence available for biosimilar products differ from that of generic products, but such clinical evidence also differs between different families of biological medicines.*

*(35) Originator biological products and biosimilar products are therefore **not identical in terms of molecular structure**, and moreover they are distinct in terms of clinical evidence available on their efficacy and safety.*

*(36) ... Upon loss of market exclusivity, if the **perceived clinical risks of switching** are not negligible, new biosimilar entrants for a given monoclonal antibody are less likely to attract patients that have already initiated treatment with the original product. In this case, **biosimilar competition takes place mainly for newly diagnosed patients that are about to initiate treatment so have not received a therapeutic drug yet**.*

(38) To the extent that new biosimilar entrants manage to attract treatment-naive patients and build their own stock of locked-in patients, they face the trade-off between continuing to price low to attract additional patients and increasing prices to exploit their stock of locked-in patients. Given their inability to price discriminate between new and locked-in patients, this trade-off weakens their incentives to aggressively compete in price for new patients. Therefore, while biosimilar competitors have an incentive to price low at entry, such incentive diminishes as they establish their position in the market, resulting in less intense price competition."

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ:
(A1) Προϊοντική (FDP)

BALLAS PELECANOS & ASSOCIATES L.P.C.

1.4. Pipeline Products (R&D)

- *NOVARTIS/ GLAXOSMITHKLINE ONCOLOGY BUSINESS (M.7275)*

(24) In its previous practice, the Commission assessed the potential competitive constraint likely to be exerted by products in Research & Development ("R&D") on existing product markets as well on possible future markets.

*(26) In line with its previous decisions, in this case the Commission considers that when research and development ("R&D") activities are assessed in terms of importance for future markets, the product market definition **can be left open**, reflecting the intrinsic uncertainty in analysing products that do not exist as yet.*

(27) In particular, the Commission considers that the product market definition for pipeline pharmaceuticals can be guided primarily by the characteristics of future products as well as by the indications to which they are to be applied.

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ:
(A2) Προϊοντική: Ανάντη Αγορές

BALLAS PELECANOS & ASSOCIATES L.P.C.

Α.2.1 Δραστική Φαρμακευτική Ουσία (API):

- *MYLAN/ ABBOTT EPD-DM (M.7379)*

(457) "APIs are produced from chemical and biological products and may be manufactured internally or sourced from external manufacturers. In past cases, the Commission considered that APIs form separate product markets upstream from the markets for FDPs."

Α.2.2. Συμφωνίες Παρασκευής Φαρμάκων (Contract Manufacturing for FDP)

- *WATSON/ACTAVIS (M.6613)*

(123) "Contract manufacturing of finished dose pharmaceuticals consists of the manufacturing under contract of finished dose pharmaceutical products, which may or may not include final packaging on behalf of third party pharmaceutical companies. This third party then goes on to market the finished products under its own label or brand(s). This definition excludes the manufacturing of active pharmaceutical ingredients, since such ingredients are not typically manufactured on a contract basis and typically may be procured from a wide variety of sources. A number of contract manufacturing markets may be defined, corresponding in each case to the pharmaceutical form which is manufactured and also in some cases the conditions of manufacture (types of API involved in the process, toxicity, sterile environment, etc.)."

Διοργάνωση: ΝΟΜΙΚΗ ΒΙΒΛΙΟΘΗΚΗ eco.nomia
Υπό την αιγίδα: Ελληνική Επιτροπή Ανταγωνισμού
Υπό τη θεσμική υποστήριξη: ΣΕΒ

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ:
(A2) Προϊοντική: Ανάντη Αγορές

BALLAS PELECANOS & ASSOCIATES L.P.C.

Α.2.3 Παραχώρηση Άδειας για Εμπορική Εκμετάλλευση (Outlicensing)

- *WATSON/ACTAVIS (M.6613)*

*(118) The parties are active in vertically related markets for the outlicensing of pharmaceuticals when one party outlicenses a pharmaceutical product to third parties which then commercialise that product under their own name, while the other party is active in the downstream market for the marketing of the same pharmaceutical in the same Member State under its own name. Usually **the licensor licenses to the licensee rights to use a dossier to obtain a marketing authorisation in one or more countries for a product**. At the beginning of the licensing arrangement, the licensor will either transfer an existing marketing authorisation to the licensee (which involves registering a name change in relation to the existing license) or manage the registration process in the name of the licensee. Alternatively the licensee can request the dossier from the licensor and manage the registration process himself.*

*(119) "Under the parties' outlicensing arrangements, the manufacturing intellectual property rights ("IPR") usually remains with the licensor for at least the first five years of the relationship, and during this time the terms of supply/licensing are essentially fixed. During this time, **the licensee will generally buy the finished product (or bulk) from the licensor on an exclusive basis and commercialise the product under its own name, using the marketing authorisation which was licensed to it by the licensor**."*

*(120) "In previous decisions the Commission considered **outlicensing as separate markets which are upstream of the markets of the finished pharmaceutical products** and that, from geographic perspective, are at least EEA wide. The Commission looked at the outlicensing of the relevant IPRs for each individual API as potentially constituting a relevant market."*

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ:
(Α3) Προϊοντική: Κατάντη Αγορές

A.3.1. Pre-Wholesale of pharmaceuticals

- *ALLIANCE BOOTS / ANDREAE-NORIS ZAHN (M.6044)*

*(6) "Pre-wholesaling is the provision of logistical services to pharmaceutical manufacturers, mainly consisting in the **warehousing and transportation** of pharmaceutical products from the manufacturer to wholesalers, hospitals and, in some instances, to pharmacies. The suppliers of pre-wholesale services do not take title to the pharmaceutical products they are storing and ownership remains with the manufacturer until delivery. Pre-wholesalers do not have a customer relationship with the intended recipient of the products but with the manufacturers who pay a fee or commission for the service."*

*(7) "According to the parties pre-wholesaling constitutes a relevant product market on its own. This market has emerged due to the outsourcing of these specific activities by manufacturers of pharmaceuticals over the last years. **Pre-wholesaling services differ from wholesaling** in that they are services provided to the manufacturers and do not concern the purchase and sale of pharmaceuticals. Pre-wholesaling **also differs from wider logistics and transportation services** because pre-wholesaling requires sector specific knowledge, and the providers need a wholesale license as well as a license for the premises where the pharmaceuticals are stored (warehousing). The services are specific to the products concerned, e.g. the services comprise temperature-controlled and humidity-regulated storage, refrigerated transit, high-security and legislation-compliant storage, recall management and labelling as well as secondary and tertiary packaging specific to pharmaceuticals."*

(9) "The Commission considers the parties' arguments for a separate market for prewholesaling services to be plausible."

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ:
(Α3) Προϊοντική: Κατάντη Αγορές

A.3.2. Wholesale of pharmaceuticals

- *McKesson / UDG Healthcare (M. 7818)*

(15) The Commission has commonly sub-divided the wholesale of pharmaceuticals on the basis of the following three categories:

a. *Categories of* ***wholesalers*** *(full-line wholesalers and short-line wholesalers)*

b. *Categories of* ***products*** *(depending on whether the medicine may be sold with prescription or over-the-counter; whether it is an originator, generic or parallel import medicine; and whether the medicine may be sold in retail pharmacies under the supervision of a pharmacist only, or also in other outlets such as supermarkets); and*

c. *Categories of* ***customers*** *(retail pharmacies, dispensing doctors and hospitals) due to different purchasing and delivery patterns.*

- *TEVA/ RATIOPHARM (M.5865)*

(451) "In previous decisions the Commission has identified a market for the ***full-line wholesale*** *of pharmaceutical products (i.e. a broad range of products encompassing pharmaceutical products available by doctor's prescription, products subject to sale by pharmacists and other pharmaceuticals as well as other products which require special storage and treatment like analgesics and highly inflammable substances).*

(452) "The Commission has also stated that due to the narrowly defined legal framework in which full-line wholesalers usually operate (i.e. the obligation to obtain specific permissions and fulfil a number of legal requirements in order to be able to operate as a full-line pharmaceutical wholesaler), their activities can be ***distinguished from*** *(i) the direct distribution of products by manufacturers to pharmacists (****direct-line****) and (ii) the activities of* ***short-line*** *distributers or* ***parallel importers****, who generally focus on a limited range of products.*

(453) "However, the Commission observed that there may exist a degree of substitutability between long and short-line wholesalers and was able to leave the market definition open."

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ:
(Β) Γεωγραφική

BALLAS PELECANOS & ASSOCIATES L.P.C.

- Τελικά Φαρμακευτικά Προϊόντα (FDP) → ΕΘΝΙΚΗ
  - CVC / TEVA'S WOMEN'S HEALTH BUSINESS (M.8675)

    (20) "…The Commission has consistently held that the market for finished pharmaceutical products is national in scope. This conclusion has been reached because of:

    (i) varying regulatory controls for pharmaceutical products;

    (ii) perceived differences in price setting and purchasing patterns/reimbursement by Member States;

    (iii) differences in national clinical guidelines, medical views and patient preferences;

    (iv) differences in brand, pack size and distribution system; and

    (v) because competition between pharmaceutical companies generally takes place at national level."
- Δραστική Φαρμακευτική Ουσία (API) → ΕΟΧ
- Outlicensing → ΕΟΧ
- Contract Manufacturing FDP → ΕΟΧ
- Wholesale → ΕΘΝΙΚΗ / Τοπική

Στην 378/2008 απόφασή της η ΕΑ έκρινε αναφορικά με την αγορά χονδρικής πώλησης των προϊόντων που διακινούνται από μια φαρμακαποθήκη προς τα φαρμακεία ότι «*ως σχετική γεωγραφική αγορά λαμβάνεται το **σύνολο της ελληνικής επικράτειας**, περιοχή στην οποία τα μέρη και οι ανταγωνιστές αυτών πωλούν τα προϊόντα τους υπό επαρκώς ομοιογενείς συνθήκες ανταγωνισμού*.»

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ:
(Γ1) Επηρεαζόμενες Αγορές: Οριζοντίως

BALLAS PELECANOS & ASSOCIATES L.P.C.

- Λόγω του πλήθους των σχετικών αγορών που προκύπτουν εξαιτίας της εθνικής διάστασης της σχετικής γεωγραφικής αγοράς των **FDPs**, ως επηρεαζόμενες αγορές στον κλάδο αυτό θεωρούνται οι ακόλουθες:

- *TEVA / PGT OTC ASSETS (M.8889)*

  (35) "In line with precedents in the pharmaceutical industry, the markets affected by the Transaction have been grouped as follows:

  *(a) **Group 1** markets, where the Parties' combined market share exceeds 35% and the increment exceeds 1%;*

  *(b) **Group 1+** markets, where **(i)** the combined market share is below 35% but only one other competitor remains on the market; or **(ii)** the combined market share exceeds 35% and the increment is below 1% but the party with the small increment is a recent entrant;*

  *(c) **Group 2** markets, where the Parties' combined market share exceeds 35% but the increment is below 1%;*

  *(d) **Group 3** markets, where the Parties' combined market share is between 20% and 35%."*

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ:
(Γ2) Επηρεαζόμενες Αγορές: Καθέτως

BALLAS PELECANOS & ASSOCIATES L.P.C.

- *TEVA/BARR (M.5295)*

  (196) When identifying vertically affected markets which may give rise to serious doubts, the Commission has focused on vertical relationships where:

  (i) either party has a market share of more than 30% in an upstream API-market and the other party has a market share of more than 5% in an ATC3 class containing that particular API, or

  (ii) either party has a market share of more than 25% in a downstream ATC3 class and the other party has market share of more than 5% of a corresponding upstream API-market.

Διοργάνωση: ΝΟΜΙΚΗ ΒΙΒΛΙΟΘΗΚΗ eco.nomia
Υπό την αιγίδα: Ελληνική Επιτροπή Ανταγωνισμού
Υπό τη θεσμική υποστήριξη: ΣΕΒ

IV. ΣΧΕΤΙΚΗ ΑΓΟΡΑ:
(Δ) Υπολογισμός Μεριδίων Αγοράς

- *TEVA/ RATIOPHARM (M.5865)*

49. *In previous cases, the Commission has primarily relied on the **value of sales recorded by IMS** as a measure of market share. Calculating market shares on the basis of value has the advantage of allowing easy aggregation of products which may be based on different active ingredients, different quantities of which may be required to achieve the same therapeutic outcome.*

50. ***However**, as noted in previous decisions, calculating market shares based on value may have certain **limitations** in genericised pharmaceuticals markets, because generic producers often charge prices which may be significantly lower than those of originators. Branded generics may also be able to command a price premium relative to non-branded ones, in particular where generic substitution of the brand does not systematically apply in pharmacies and prescriptions are not necessarily based on the international non-proprietary name (INN) of the active ingredient(s) concerned. In such cases, shares based on value may sometimes differ significantly from market shares based on volume. For molecule markets, volume shares can easily be assessed based on weight of active ingredient. For markets consisting of a number of molecules, a **volume market share** would need to be calculated normalized to some measure of therapeutic value such as days of treatment.....*

52. *It should be further noted that the indication of market shares by volume may only make sense when markets are looked at on the basis of dosage and/or galenic form. Although, as discussed, distinctions of this type are often relevant also for market definition purposes and have been considered in the assessment, their relevance is not necessarily systematically the case and where it is not, neither measure taken alone is fully satisfactory.*

V. Αξιολόγηση Συγκεντρώσεων:
ΔΥΝΗΤΙΚΟΣ ΑΝΤΑΓΩΝΙΣΜΟΣ & ΚΑΙΝΟΤΟΜΙΑ (PIPELINE COMPETITION)

BALLAS PELECANOS & ASSOCIATES L.P.C.

- Κατά την εξέταση μιας συγκέντρωσης αξιολογούνται και οι επιπτώσεις που θα επιφέρει στα **υπό ανάπτυξη προϊόντα/τεχνολογίες** που είτε θα:
  - αντικαταστήσουν ήδη υπάρχοντα, είτε θα
  - δημιουργήσουν νέα ζήτηση

- *BMS/Celgene (M.9294)*

  (20) "The Commission considers that a concentration may not only affect competition in existing markets, but also competition in innovation and new product markets. This may be the case when a concentration concerns entities currently developing new products or technologies which either may one day replace existing ones or which are being developed for a new intended use and will therefore not replace existing products but create a completely new demand."

  *(21) "In the pharmaceutical industry, the process of innovation is structured in such a way that it is typically possible at an early stage of clinical trials to identify competing research programmes (or "**pipeline" programmes**). Competing pipeline programmes can be defined as R&D efforts aimed at developing substitutable products and having similar timing. **The timing of a research programme should be assessed by reference to the stage of the on-going preclinical or clinical trials**."*

V. Αξιολόγηση Συγκεντρώσεων:
ΔΥΝΗΤΙΚΟΣ ΑΝΤΑΓΩΝΙΣΜΟΣ & ΚΑΙΝΟΤΟΜΙΑ (PIPELINE COMPETITION)

BALLAS PELECANOS & ASSOCIATES L.P.C.

- Τα **4 Στάδια** Κλινικών Δοκιμών Ανάπτυξης Νέου Φαρμακευτικού Προϊόντος:
  - *J&J/ACTELION (M.8401)*
    The Phases of Clinical Development can be described as follows:
    - **Phase I** starts with the initial administration of a new drug into humans generally on healthy volunteers. It typically involves one or a combination of the following aspects: estimation of initial safety and tolerability, characterisation of a drug's absorption, distribution, metabolism, and excretion, and early measurement of drug activity.
    - **Phase II** usually starts with the initiation of studies to explore therapeutic efficacy in patients. Studies in Phase II are typically conducted on a small group of patients that are closely monitored. An important goal for this phase is to determine the dose(s) and regimen for Phase III trials.
    - **Phase III** usually starts with the initiation of studies to demonstrate, or confirm therapeutic benefit. Studies in Phase III are designed to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use in the intended indication and recipient population. These studies are intended to provide an adequate basis for marketing approval.
    - **Phase IV** begins after drug approval.

V. Αξιολόγηση Συγκεντρώσεων:
ΔΥΝΗΤΙΚΟΣ ΑΝΤΑΓΩΝΙΣΜΟΣ & ΚΑΙΝΟΤΟΜΙΑ (PIPELINE COMPETITION)

BALLAS PELECANOS & ASSOCIATES L.P.C.

Basic research	Research	Development				Market launch & phase IV: post-market surveillance
	Drug discovery	Pre-clinical	Clinical trials		Regulatory approval	
			Phase I	Phase II	Phase III	
	5,000-10,000 compounds	250 compounds	5 compounds			1 compound *new drug*
	- Target identification	- *In vitro* & *in vivo* testing - Efficacy	- Healthy volunteers - Safety & reaction in humans	- Sick volunteers	- Test for infrequent side-effects	
	3-5 years	1-2 years	6-7 years			1-2 years
PoS	-	67%	46%	19%	77%	n.a.
Cost	17,5%	4,8%	8,6%	13,3%	24,4%	5,7%

Πηγή: Camille Lammens

V. Αξιολόγηση Συγκεντρώσεων:
ΔΥΝΗΤΙΚΟΣ ΑΝΤΑΓΩΝΙΣΜΟΣ & ΚΑΙΝΟΤΟΜΙΑ (PIPELINE COMPETITION)

BALLAS PELECANOS & ASSOCIATES L.P.C.

1.1. Late-Stage Pipeline Products

- *TEVA/ RATIOPHARM (M.5865)*

(426) *"In previous decisions relating to originator pipelines, a pipeline was considered to be in a sufficiently advanced stage of development to be considered as a possible competitive constraint when it reached clinical trials (**Phase III**). As noted above, the approval of biosimilars also requires the performance of clinical trials. This notwithstanding, the development process is different to that of originator pharmaceuticals. For this reason the market investigation aimed to verify at which stage of the biosimilar development process eventual launch could be considered sufficiently certain for the pipeline to be considered a potential competitive constraint.*

(427) *The market investigation indicated that the most difficult part of the process was to achieve the stage just before clinical trials, and, in particular, to show proof of similarity. **Once the project is in a stage that it can enter clinical trials, according to the market investigation, there is a good chance of eventual launch."***

V. Αξιολόγηση Συγκεντρώσεων:
ΔΥΝΗΤΙΚΟΣ ΑΝΤΑΓΩΝΙΣΜΟΣ & ΚΑΙΝΟΤΟΜΙΑ (PIPELINE COMPETITION)

BALLAS PELECANOS & ASSOCIATES L.P.C.

- Συνεκτίμηση νέων προϊόντων με δυνατότητα εμφάνισης στην αγορά εντός 2 χρόνων
  - *PFIZER HOSPIRA (M.7559)*

  (269) *"Generic companies usually develop a number of pipeline generic drugs which are intended to compete with originators which go off-patent. In assessing **pipeline** competition, the Commission has previously focused on instances where one party is planning to enter a market with a new product within a period of **two years** and the other party (or the parties combined) has a market share of 35% or more on any possible market definition where the pipeline products and existing products overlap."*

- **Όμως**, παρατηρείται σταδιακά τάση συνεκτίμησης ως δυνητικά ανταγωνιστικών προϊόντων που βρίσκονται σε πρώιμο στάδιο ανάπτυξης και για τα οποία υπάρχει μεγαλύτερη αβεβαιότητα για το εάν θα περάσουν επιτυχώς τα επόμενα στάδια κλινικών δοκιμών και θα κυκλοφορήσουν τελικά στην αγορά.

V. Αξιολόγηση Συγκεντρώσεων:
ΔΥΝΗΤΙΚΟΣ ΑΝΤΑΓΩΝΙΣΜΟΣ & ΚΑΙΝΟΤΟΜΙΑ (PIPELINE COMPETITION)

1.2. Early-Stage Pipeline Products & Cannibalisation

- *NOVARTIS/ GLAXOSMITHKLINE ONCOLOGY BUSINESS (M.7275)*

*(103) "Roche is currently conducting only a **Phase II** clinical trial for its B-Raf inhibitor…..*

*(104) …Post-transaction, the Notifying Party will internalise that investing in one of the clinical research programs can be expected to **cannibalise** future sales of its other clinical research program. In light of the few competing research programs in this area, the transaction is likely to significantly reduce the Notifying Party's incentive to continue investing substantial amounts in R&D on both MEK and B-Raf clinical research programs in parallel.*

*(108) Pipeline products at **early stages** of clinical development face higher uncertainty as to their future clinical use than pipeline products at advanced stages of development. **However, the uncertainty about the outcome of on-going clinical research does not preclude an assessment of the likely effects of the Proposed Transaction on the development of such pipeline products.** Whatever the level of uncertainty might be, a reduction in the efforts invested to bring forward a clinical research program can reasonably be expected to reduce its probability of success. Ultimately, the abandonment of an entire clinical research program for a certain product or products would have as necessary consequence the failure in bringing such products to the market."*

V. Αξιολόγηση Συγκεντρώσεων:
ΔΥΝΗΤΙΚΟΣ ΑΝΤΑΓΩΝΙΣΜΟΣ & ΚΑΙΝΟΤΟΜΙΑ (PIPELINE COMPETITION)

1.2. Early-Stage Pipeline Products & Cannibalisation

- *J&J / ACTELION (M.8401)*

(50) *"If the pipeline product of one of the Parties is likely to capture significant revenues from the competing product of the other Party, the merged entity will likely have the* ***incentives to discontinue, delay or re-orient one of the two pipelines****. Indeed, from the perspective of each innovator, the expected loss of profits on the products of the other party (i.e. because of sales* ***cannibalisation****) adds to the opportunity cost of innovating, making it more likely that an early pipeline product is suppressed, deferred or re-directed (particularly in the presence of significant development and commercialisation costs).*

(53) *…Consumers, in particular doctors and patients, would suffer from the* ***loss of product variety*** *and* ***reduced intensity of future product market competition****, with the likely resultant price increases, in the market where the discontinued, delayed or re-oriented product would have been introduced but for the Transaction."*

V. Αξιολόγηση Συγκεντρώσεων:
ΔΥΝΗΤΙΚΟΣ ΑΝΤΑΓΩΝΙΣΜΟΣ & ΚΑΙΝΟΤΟΜΙΑ (PIPELINE COMPETITION)

BALLAS PELECANOS & ASSOCIATES L.P.C.

➢ **Διάκριση μεταξύ *"cannibalization" και "Innovation competition"***

- *Dow/DuPont (M.7932)*

(2108) *"The Commission further notes that its theory of harm rests on the broader notion of innovation competition rather than on the notion of cannibalisation of existing products. This is because **cannibalisation** is often meant to refer to a diversion of sales from one or several existing products to an innovative product sold by the same firm. **Innovation competition**, instead, more broadly refers to the extent to which innovative products of one firm may divert sales and profits from both existing **and other innovative future products** of rival firms. Through innovation, rival firms therefore impose a negative externality on each other. Accordingly, the Commission notes that even if innovation were to involve no cannibalisation of the sales of existing products, a merger between two out of a limited number of innovators in a market could reduce innovation incentives, by leading to the partial internalisation of the impact of innovation competition between the merging parties. This would likely be the case if, absent the merger, firms would compete with innovative products in some markets with a sufficient likelihood, diverting existing and future sales from each other."*

V. Αξιολόγηση Συγκεντρώσεων:
ΔΥΝΗΤΙΚΟΣ ΑΝΤΑΓΩΝΙΣΜΟΣ & ΚΑΙΝΟΤΟΜΙΑ (PIPELINE COMPETITION)

BALLAS PELECANOS & ASSOCIATES L.P.C.

1.3. Innovation Spaces

- *Dow/DuPont (M.7932)*

(352) *"In conclusion, in order **to assess innovation competition**, the Commission will both consider metrics of innovation taking place at industry level, as well as innovation taking place in spaces consisting of groupings of crop/pest combinations (as will be defined specifically for the areas where the Parties overlap in Section V.8.8)."*

(1) *At the **level of innovation spaces**, the overlaps between the Parties' lines of research and early pipeline products as well as between lines of research and early pipeline products of a Party that will compete in a market where the other Party is an existing or potential supplier; and*

(2) *At the **industry level**, the overlap between the Parties' respective global R&D organisations, that is the resources, personnel, facilities, and other tangible and intangible assets dedicated to research, development and registration of new active ingredients (including lines of research, field testing facilities, registration capabilities).*

(2162) *However, the R&D players do not innovate for all the product markets composing the entire crop protection industry at the same time. They also do not innovate randomly without **targeting specific spaces** within that industry. When setting up their innovation capabilities and conducting their research, they target specific innovation spaces which are upstream of lucrative product markets and product markets which are of strategic interest for the R&D player in question. **In order to assess innovation competition, it is thus important to consider the spaces in which this innovation competition occurs**."*

V. Αξιολόγηση Συγκεντρώσεων:
ΔΥΝΗΤΙΚΟΣ ΑΝΤΑΓΩΝΙΣΜΟΣ & ΚΑΙΝΟΤΟΜΙΑ (PIPELINE COMPETITION)

BALLAS PELECANOS & ASSOCIATES L.P.C.

- ***Βραχυχρόνιες & μακροχρόνιες αρνητικές επιπτώσεις στον ανταγωνισμό για καινοτομία***

- *Dow/DuPont (M.7932)*

*(3056) "In the case of the Transaction, the Commission considers that a **first form of harm to innovation competition** would likely be the discontinuation of overlapping lines of research and early pipeline products which target the same innovation spaces. This effect would likely be a **short-term effect** of the Transaction for those **overlapping** lines of research and early pipeline products that would likely be discontinued, deferred or redirected very soon after the merger is implemented as a result of the integration efforts following the Transaction. The Commission finds it reasonable that the integration efforts are [post-merger integration information].*

*(3057) "The Commission finds that a **second form of harm** would result from the **lower overall incentives** of the merged entity to innovate as compared to the merging parties separately before the transaction. This is likely to be a **medium and long term structural effect** of the transaction going beyond the mere discontinuation of current innovation projects. The concern here is that in the medium and long-term, because of the lack of rivalry incentives to innovate, the merged entity would pursue less discovery work, less lines of research, less development and registration work and ultimately bring less innovative AIs to the market than the merging parties would have done absent the transaction."*

V. Αξιολόγηση Συγκεντρώσεων:
ΔΥΝΗΤΙΚΟΣ ΑΝΤΑΓΩΝΙΣΜΟΣ & ΚΑΙΝΟΤΟΜΙΑ (PIPELINE COMPETITION)

BALLAS PELECANOS & ASSOCIATES L.P.C.

➢ ΣΥΝΟΨΗ: Τα 4 Επίπεδα Ανάλυσης των επιπτώσεων μιας συγκέντρωσης

- *BMS/Celgene (M.9294)*

*(22) "In line with the past decisional practice in the pharmaceutical sector and the Commission's decisions in Dow/Dupont and Bayer/Monsanto, the Commission has taken into account a **four-layer competitive assessment framework**, which corresponds to the overlaps between the parties' activities in terms of:*

(a) ***Actual*** *(product and price)* ***competition****, assessing the overlaps between the parties' existing (marketed) products;*

(b) ***Potential*** *(product and price)* ***competition****, assessing the overlaps (i) between the parties' existing (marketed) and pipeline products at advanced stages of development and (ii) between the parties' pipeline products at* ***advanced stages of development****. For pharmaceutical products, the Commission in principle considers programmes in* ***Phase II and III*** *clinical trials as being at an advanced stage of development;*

(c) *Innovation competition in relation to the parties'* ***ongoing pipeline products****, assessing the risk of significant loss of innovation competition resulting from the discontinuation, delay or redirection of the overlapping pipelines (including* ***early stage pipelines****); and*

(d) *Innovation competition in relation to the capability to innovate in certain* ***innovation spaces****, assessing the risk of a significant loss of innovation competition resulting from a structural reduction of the overall level of innovation."*

V. Αξιολόγηση Συγκεντρώσεων:
ΔΥΝΗΤΙΚΟΣ ΑΝΤΑΓΩΝΙΣΜΟΣ & ΚΑΙΝΟΤΟΜΙΑ (PIPELINE COMPETITION)

BALLAS PELECANOS & ASSOCIATES L.P.C.

- **Κριτήρια αξιολόγησης των επιπτώσεων μιας συγκέντρωσης στον ανταγωνισμό στην καινοτομία**
  - Η καινοτομία αποτελεί σημαντική παράμετρο του ανταγωνισμού στον φαρμακευτικό κλάδο
  - Έντονη παρουσία του φαινομένου της προστασίας των επιχειρήσεων μέσω δικαιωμάτων πνευματικής ιδιοκτησίας
  - Οι συμμετέχουσες επιχειρήσεις είναι σημαντικοί και άμεσοι ανταγωνιστές στην καινοτομία με παρεμφερείς ικανότητες έρευνας και ανάπτυξης (R&D)
  - Η δομή της αγοράς που αφορά δραστηριότητες έρευνας και ανάπτυξης (R&D) έχει χαρακτηριστικά ολιγοπωλίου.
  - Έλλειψη αντίδρασης άλλων ανταγωνιστών που καινοτομούν
  - Εμπόδια εισόδου στην αγορά

VI. Διορθωτικά Μέτρα (Remedies)

- Προτίμηση για διαρθρωτικές δεσμεύσεις (structural remedies) μέσω μεταβίβασης δραστηριότητας
- Προσδιορισμός του κατάλληλου εύρους των δεσμεύσεων αναφορικά με τα επιμέρους στοιχεία που πρέπει να μεταβιβασθούν:
  - Δικαιώματα πνευματικής ιδιοκτησίας (πλήρης μεταβίβαση ή κοινή εκμετάλλευση;)
  - Δεδομένα & έγγραφα
  - Παροχή πρόσβασης σε εγκαταστάσεις R&D μέσω σύμβασης παροχής υπηρεσιών
  - Αποτελέσματα κλινικών δοκιμών
  - Τεχνογνωσία (και σχετικές υποστηρικτικές υπηρεσίες όπως π.χ. εκπαίδευση)
  - Προσωπικό (επιστήμονες, μηχανικούς, διευθυντές τμήματος, κλπ.)
  - Σχετικές συμβάσεις με τρίτα μέρη (π.χ. συμβάσεις προμήθειας πρώτων υλών)
  - Μεταβίβαση υφιστάμενων προϊόντων
- Εύρεση αρχικού αγοραστή (Up-front buyer clause)

VII. Σχόλια & Παρατηρήσεις

(1) **Πόσες** ανταγωνιστικές τεχνολογίες/έρευνες καινοτομίας πρέπει να υπάρχουν προκειμένου μια συγκέντρωση να μην επιφέρει αρνητικές συνέπειες στον ανταγωνισμό για καινοτομία;

- *Κατευθυντήριες γραμμές για την εφαρμογή του άρθρου 101 της Συνθήκης για τη λειτουργία της Ευρωπαϊκής Ένωσης σε συμφωνίες μεταφοράς τεχνολογίας:*

*157. «Προκειμένου να προωθηθεί η προβλεψιμότητα πέραν της εφαρμογής του ΚΑΚΜΤ και να περιορισθεί η εμπεριστατωμένη εξέταση μόνο στις περιπτώσεις που είναι πιθανόν να εμφανίζουν πραγματικά προβλήματα ανταγωνισμού, η Επιτροπή υιοθετεί την άποψη ότι, απουσία περιορισμών ιδιαίτερης σοβαρότητας, δεν είναι πιθανόν να υφίσταται παράβαση του άρθρου 101 της Συνθήκης όταν υπάρχουν **τέσσερις ή περισσότερες ανεξάρτητα ελεγχόμενες τεχνολογίες** πλέον των τεχνολογιών που ελέγχουν οι συμβαλλόμενοι της συμφωνίας και οι οποίες μπορούν να υποκαταστήσουν την παραχωρούμενη τεχνολογία με παραπλήσιο κόστος για τον χρήστη.*

*Για να εκτιμηθεί κατά πόσον υπάρχει σε επαρκή βαθμό **δυνατότητα υποκατάστασης** αυτής της τεχνολογίας, πρέπει να λαμβάνεται υπόψη η σχετική **εμπορική ισχύς** των εν λόγω τεχνολογιών. Η ανταγωνιστική πίεση που επιβάλλει μια τεχνολογία περιορίζεται εάν δεν αποτελεί εμπορικά βιώσιμη εναλλακτική λύση στην παραχωρούμενη τεχνολογία.»*

- *MEDTRONIC/ COVIDIEN (M.7326)*

*(186) "Currently, in Europe, **10 companies** have a DCB with CE mark, namely Medtronic (described in Section IV.2.3.6.c.i), Aachen Resonance, Atrium Medical, Bard, Biotronik, Boston Scientific, Cardionovum, Cook Medical, Eurocor and iVascular (described in Section IV.2.3.6.c.ii).*

(187) Covidien, on the other hand, only has a pipeline DCB called Stellarex which is described in Section IV.2.3.6.c.iii.

*(228) …..the market investigation further pointed out that these other DCBs are **relatively new products which lack sufficient data to prove reliability and efficacy**.*

*(231) …. It therefore appears that the **existing competitors would not be in a position to exert sufficient competitive pressure** on the merged entity on the DCB market post-Transaction."*

VII. Σχόλια & Παρατηρήσεις

(2) Δικαιολογείται η διαφορετική αντιμετώπιση της χρονικής διάστασης που λαμβάνεται υπόψιν για την διαπίστωση της ύπαρξης ή μη **δυνητικού ανταγωνισμού**; Πότε ασκεί μια τεχνολογία/έρευνα για καινοτομία ανταγωνιστική πίεση σε μια άλλη;

❖ Δυνητικός ανταγωνισμός **από τρίτους ως ανταγωνιστική πίεση** → **Μόνο βραχυπρόθεσμα**

- *PFIZER/HOSPIRA (M.7559)*

*(51) "Finally, the other competitors identified by the Notifying Party such as Epirus, Amgen/Actavis and Dr. Reddy's, do not have an infliximab biosimilar in **advanced stages of development**, and are therefore not expected to become a competitive constraint in the EEA in the **foreseeable future**."*

❖ Δυνητικός ανταγωνισμός **μεταξύ των μερών ως θεωρία βλάβης** → **Βραχυπρόθεσμα ΚΑΙ μακροπρόθεσμα**

- *NOVARTIS/ GLAXOSMITHKLINE ONCOLOGY BUSINESS (M.7275)*

*(108) "Pipeline products at **early stages** of clinical development face higher uncertainty as to their future clinical use than pipeline products at advanced stages of development. **However, the uncertainty about the outcome of on-going clinical research does not preclude an assessment of the likely effects of the Proposed Transaction on the development of such pipeline products."***

VII. Σχόλια & Παρατηρήσεις

(3) Ανταποκρίνεται η διαρκής διεύρυνση του πλαισίου ανάλυσης των επιπτώσεων στην καινοτομία στην **οικονομική πραγματικότητα** που επικρατεί στον κλάδο της φαρμακοβιομηχανίας;

- Μετατόπιση της δραστηριότητας έρευνας και ανάπτυξης (R&D) από μεγάλες φαρμακευτικές εταιρείες σε μικρές biotech επιχειρήσεις λόγω τεχνολογικής προόδου, όπως:
  - η χρήση αλγορίθμων που επιτρέπει πλέον πολλά πειράματα να διεξάγονται σε υπολογιστή αντί σε εργαστήριο
  - sequencing DNA τεχνολογίες έχουν μειώσει σημαντικά το κόστος εντοπισμού γενετικών μορίων (genetic mutations) που μπορούν να οδηγήσουν στη δημιουργία νέου φαρμάκου
- Η απάντηση δίνεται από την οικονομική θεωρία περί **εξειδίκευσης και συγκριτικού πλεονεκτήματος** (Specialisation & Comparative Advantage)
  - Οι μεγάλες φαρμακευτικές εταιρείες επικεντρώνονται στις δραστηριότητες που απαιτούν μεγάλους πόρους διαθέσιμου κεφαλαίου και εμπειρία, όπως οι κλινικές δοκιμές στα τελευταία στάδια ανάπτυξης ενός φαρμάκου, η λήψη άδειας για την κυκλοφορία του φαρμάκου και η εμπορία του φαρμάκου, ενώ
  - Οι μικρές biotech επιχειρήσεις επικεντρώνονται στα πρώιμα στάδια έρευνας για την ανάπτυξη ενός νέου φαρμάκου
- Συνεπώς, παρατηρείται πλέον μετάβαση από την τάση διατήρησης εσωτερικού τμήματος έρευνας και ανάπτυξης στην ανάθεση της δραστηριότητας αυτής σε τρίτες επιχειρήσεις μικρού μεγέθους (from internal to external R&D)

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(4) Είναι σύμφωνη η τάση της διαρκούς διεύρυνσης του πλαισίου ανάλυσης των επιπτώσεων μιας συγκέντρωσης στην καινοτομία με το εφαρμοζόμενο **αποδεικτικό μέτρο**;

- *Υπόθεση Tetra Laval BV κατά Επιτροπής (T-5/02)*

*(331) «…. **το γεγονός και μόνον ότι η Tetra κατέχει «τεχνογνωσία» και «τεχνική υπεροχή»** στον τομέα των ασηπτικών χάρτινων κουτιών **και η SIG δεν μπορεί επί του παρόντος «να ανταγωνιστεί** το σύστημα αδιαλείπτου παραγωγής ασηπτικών χάρτινων κουτιών της Tetra» (αιτιολογική σκέψη 218) **δεν αρκεί για να αποδείξει ότι η SIG ή οι άλλοι ανταγωνιστές της δεν έχουν τη δυνατότητα να ωφεληθούν από ενδεχόμενη απόφαση της νέας οντότητας να εισάγει λιγότερες καινοτομίες** στον τομέα των χάρτινων κουτιών. Η μνεία της Επιτροπής κατά την επ' ακροατηρίου συζήτηση στο σημαντικό κόστος των καινοτομιών στις επίδικες αγορές, αν και λυσιτελής και πιθανότατα ορθή, **δεν μπορεί καθαυτή να δικαιολογήσει** το συμπέρασμα της Επιτροπής ότι οι ανταγωνιστές της Tetra δεν έχουν τη δυνατότητα να ωφεληθούν από την απόφαση της νέας οντότητας να εισάγει λιγότερες καινοτομίες.»*

- *Υπόθεση Επιτροπή κατά Tetra Laval BV (C-12/03)*

*(44) "The analysis of a 'conglomerate-type' concentration is a prospective analysis in which, first, the **consideration of a lengthy period of time in the future** and, secondly, the leveraging necessary to give rise to a significant impediment to effective competition mean that **the chains of cause and effect are dimly discernible, uncertain and difficult to establish**. That being so, the quality of the evidence produced by the Commission in order to establish that it is necessary to adopt a decision declaring the concentration incompatible with the common market is particularly important, since that evidence must support the Commission's conclusion that, if such a decision were not adopted, the economic development envisaged by it would be plausible."*

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- *Υπόθεση CK Telecoms UK κατά Επιτροπής (T-399/16)*

*(111) «Ωστόσο, **όσο πιο μακρόπνοη είναι η ανάλυση** των προοπτικών εξέλιξης της αγοράς και **όσο πιο δυσδιάκριτες, αβέβαιες και δυσαπόδεικτες είναι οι σχέσεις αιτίου και αποτελέσματος τόσο σημαντικότερη καθίσταται η ποιότητα των αποδεικτικών στοιχείων** που προσκομίζει η Επιτροπή προκειμένου να αποδείξει την αναγκαιότητα λήψης απόφασης η οποία κηρύσσει μια συγκέντρωση μη συμβατή με την εσωτερική αγορά (πρβλ. απόφαση της 15ης Φεβρουαρίου 2005, Επιτροπή κατά Tetra Laval, C-12/03 P, EU:C:2005:87, σκέψη 44). Με άλλα λόγια, **όσο πιο περίπλοκη ή αβέβαιη είναι η θεωρία περί ζημίας** που διατυπώνεται προς τεκμηρίωση της σημαντικής παρακώλυσης του αποτελεσματικού ανταγωνισμού που προβάλλεται κατά μιας πράξης συγκέντρωσης ή **όσο πιο δυσαπόδεικτη είναι η σχέση αιτίου και αποτελέσματος** από την οποία απορρέει η θεωρία αυτή **τόσο πιο απαιτητικός** πρέπει να είναι ο δικαστής της Ένωσης κατά τη συγκεκριμένη **εξέταση των αποδεικτικών στοιχείων** που προσκομίζει συναφώς η Επιτροπή.*

*(118) Στο πλαίσιο της ανάλυσης μιας σημαντικής παρακώλυσης του αποτελεσματικού ανταγωνισμού, η ύπαρξη της οποίας συνάγεται από μια δέσμη αποδεικτικών στοιχείων και ενδείξεων και στηρίζεται σε πλήθος θεωριών περί ζημίας, η Επιτροπή οφείλει να προσκομίσει **επαρκείς αποδείξεις προκειμένου να αποδείξει με σοβαρή πιθανότητα** την ύπαρξη σημαντικών παρακωλύσεων κατόπιν της συγκέντρωσης. Επομένως, η απαίτηση περί αποδείξεων είναι εν προκειμένω **αυστηρότερη** από εκείνη σύμφωνα με την οποία η σημαντική παρακώλυση του αποτελεσματικού ανταγωνισμού είναι «περισσότερο πιθανή παρά απίθανη», με βάση τη «στάθμιση πιθανοτήτων», όπως υποστηρίζει η Επιτροπή. Αντιθέτως, είναι **λιγότερο αυστηρή** σε σύγκριση με τη στηριζόμενη στην «έλλειψη εύλογης αμφιβολίας»*

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(5) Λαμβάνονται υπόψιν κατά την εξέταση μιας συγκέντρωσης οι επιπτώσεις που θα επιφέρει σε **θέματα δημοσίου συμφέροντος**;

→ Το Άρθρο 21(4) Κανονισμού Συγκεντρώσεων προβλέπει την δυνατότητα συνεκτίμησης επιπτώσεων σε θέματα δημοσίου συμφέροντος μόνο από τα Κράτη-Μέλη.

- *Illumina/GRAIL (M.10188)*

Η προστασία της δημόσιας υγείας ως ωφέλεια δημοσίου συμφέροντος ικανή να αντισταθμίσει τις αρνητικές συνέπειες μιας συγκέντρωσης στον ανταγωνισμό;

Illumina's Chief Executive Francis deSouza states:

*"The stakes are so high in terms of the number of lives that could be saved and the **public health benefit** of getting this test out broadly into the population and making it more accessible to people around the world... We felt the moral obligation to exercise our right and challenge this process this time."*

Ευχαριστώ για την προσοχή σας!

BALLAS PELECANOS & ASSOCIATES L.P.C.

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