

The role of the courts in pharma enforcement – Servier and other recent developments

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Commission Decision C(2014) 4955 final, 9 July 2014

- Servier infringed Article 102 by devising and implementing an exclusionary strategy covering the perindopril formulation market in France, the Netherlands, Poland and the United Kingdom and the market for perindopril API technology via a technology acquisition and five reverse payment patent settlement agreements.

- Fine 41.270.000 Eur

General Court, 12 Dec 2018

- L'article 6 de la décision C(2014) 4955 final est annulé

Commission Decision C(2014) 4955 fi

(1) Perindopril is a so-called angiotensin converting enzyme (ACE) inhibitor used for the treatment of cardiovascular diseases e.g. high blood pressure. Once confirmed as a successful treatment for a patient in an initial trial period, the patient typically takes the medicine over many years and is unlikely to switch to an alternative medicine, even when these alternatives become significantly cheaper than perindopril due to generic entry.

General Court, 12 Dec 2018

1. **Périndopril**

2 Servier a mis au point le périndopril, médicament indiqué en médecine cardiovasculaire, principalement destiné à lutter contre l'hypertension et l'insuffisance cardiaque, par le biais d'un mécanisme d'inhibition de l'enzyme de conversion de l'angiotensine (ci-après l'« ECA »).

Learnings from the Servier case

- No two cases are equal. In Astra, PPI's vs H2 Blockers. In Servier, Perindopril vs ACE inhibitors.
- First-in-class products and "me-too's" likely to be part of the same product market:
  - Newcomers have to show incremental value to get a premium price and to compete for prescriptions, and
  - All of them normally exerce relevant competition constraints among themselves.



Statins market Spain

Simvastatine	10 mg	28 tabs	0,95	1990	2001
139 SKU's	20 mg	28 tabs	1,58		
	40 mg	28 tabs	2,17		
Lovastatine	20 mg	28 tabs	2,5	1990	2000
30 SKU's	40 mg	28 tabs	3,92		
Pravastatine	10 mg	28 tabs	4,07	1991	2003
85 SKU's	20 mg	28 tabs	8,15		
	40 mg	28 tabs	16,3		
Atorvastatine	10 mg	28 tabs	4,61	1997	2008
177 SKU's	20 mg	28 tabs	9,21		
	40 mg	28 tabs	18,42		
Fluvastatine	20 mg	28 tabs	5	2002	2008
26 SKU's	40 mg	28 tabs	9,99		
	80 mg	28 tabs	19,98		
Rosuvastatine	5 mg	28 tabs	5,25	2008	2015
79 SKU's	10 mg	28 tabs	10,51		
	20 mg	28 tabs	21,01		
Pitavastatine	1 mg	28 tabs	20,79	2010	
8 SKU's	2 mg	28 tabs	28,54		
	4 mg	28 tabs	42,8		

Some questions still open

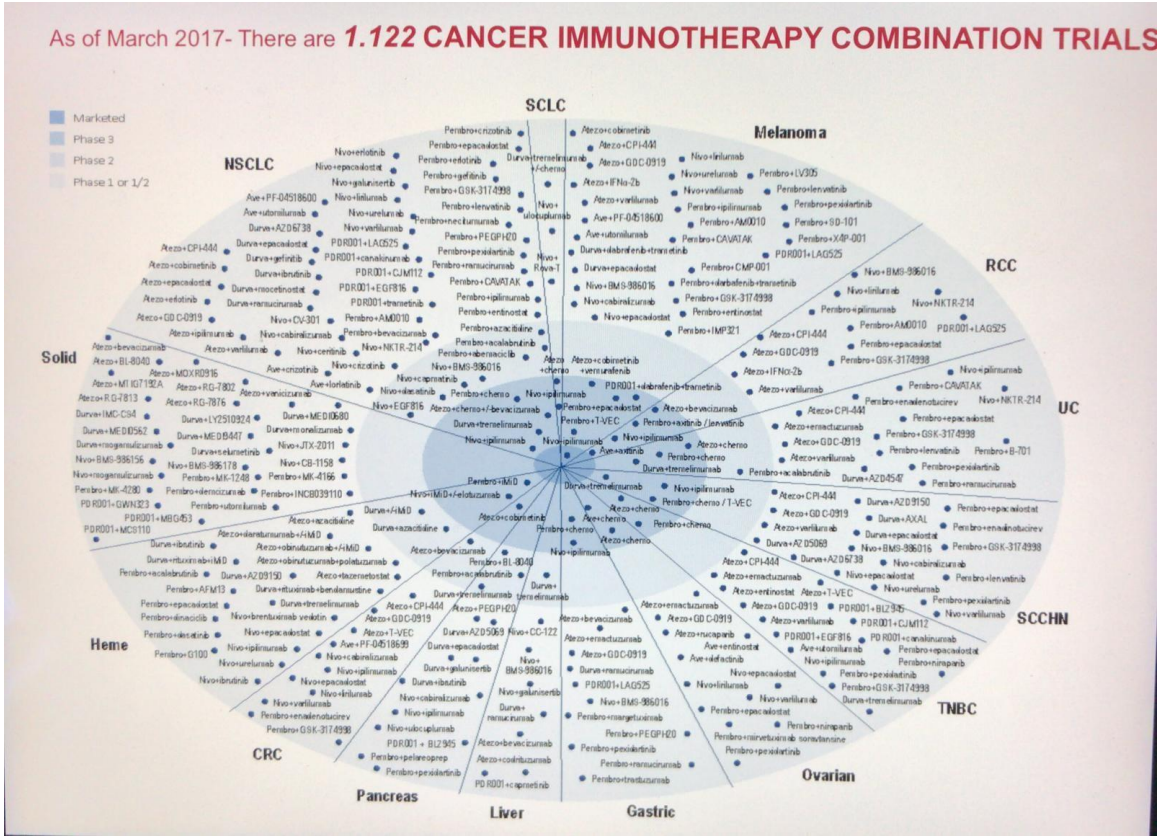
1. Interchangeable - Comparable - Substitutable - Therapeutically equivalent

- Interchangeability as a tool for homogeneous groups systems (i.e. tenders for retail pharmacy products).
- Comparability as a tool for reference price systems based on cost of DDD (Defined Daily Dosage).
- Substitution by the pharmacist is different from selection by prescribers among therapeutic equivalent alternatives.
- The role of patients in prescribing decissions likely to increase in the future.
- Non-substitutable products may well be in the same relevant product market (i.e. insulins and other biologicals).

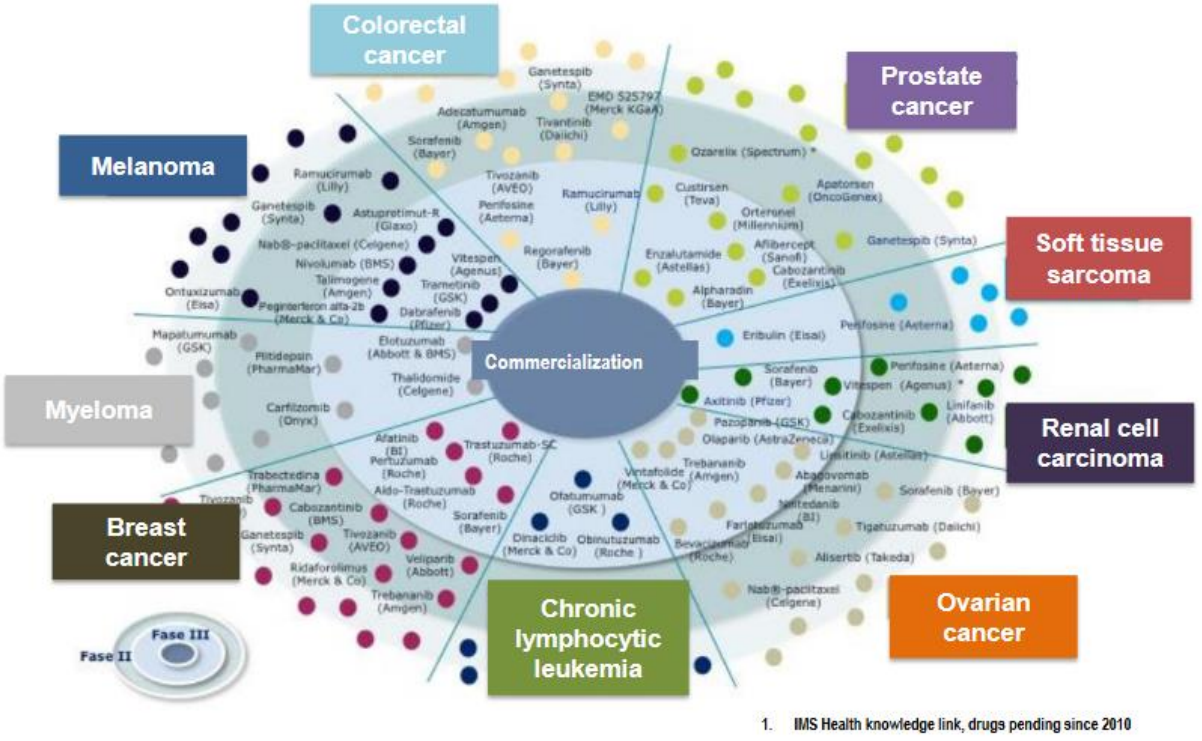
Some questions still open

2. Complex hospital use products deserve special attention

- A new stakeholder (Hospital managerial positions) comes into play ... and they care a lot about prices.
- Tenders need to be adequate to meet prescribers/patient needs, so individual lots may be required. How this impacts in market definition remains to be seen, but likely to move towards narrow markets.
- Basic information on product characteristics is going to be much more restricted. Orphan drugs may be a market per se or not (products that provide significant benefit to patients), and competition re development is ...



Courtesy of Dr. A. Gilabert, Catalan Health Consortium



Courtesy of Dr. A. Gilabert, Catalan Health Consortium

Some questions still open

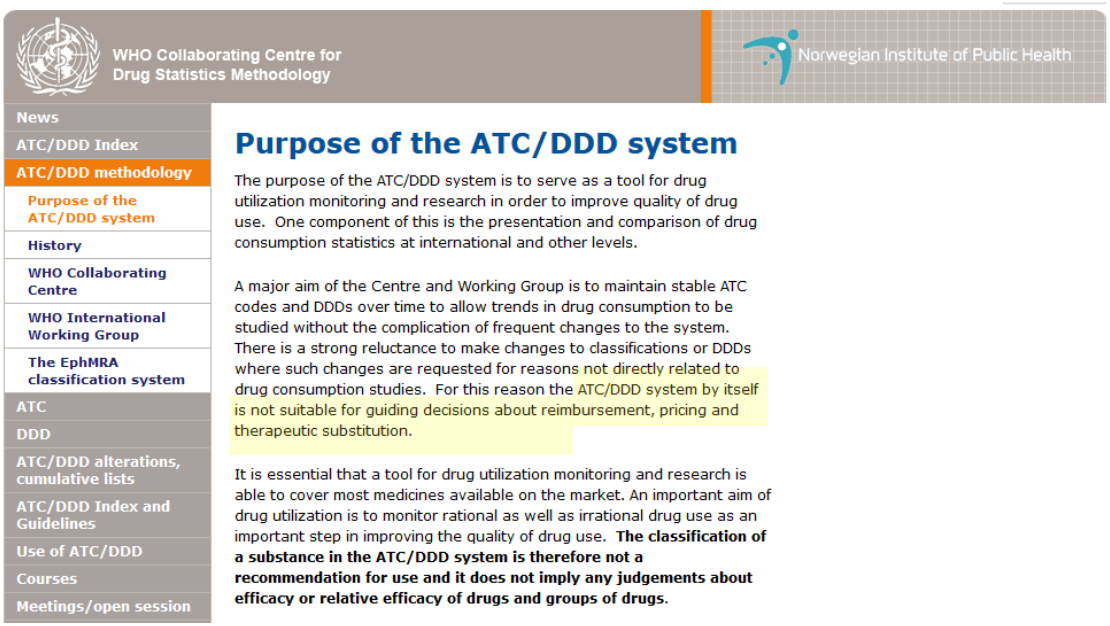
3. Pharma may be different ...

- Products require a MA.
- Strict controls/audits on manufacturing.
- Relevant variations to a MA require administrative approval.
- Price fixed by payor with inmense purchase power.
- Promotion/advertising/distribution and retail channels restrictions.
- MAH must ensure continuity in supply and withdrawal of products from the market may require approval.

... but be careful of side effects.

Some questions still open

4. Need to reconsider role of ATC classification (even if limited....)



WHO Collaborating Centre for Drug Statistics Methodology

Norwegian Institute of Public Health

- News
- ATC/DDD Index
- ATC/DDD methodology
  - Purpose of the ATC/DDD system
  - History
  - WHO Collaborating Centre
  - WHO International Working Group
  - The EphMRA classification system
- ATC
- DDD
- ATC/DDD alterations, cumulative lists
- ATC/DDD Index and Guidelines
- Use of ATC/DDD
- Courses
- Meetings/open session

Purpose of the ATC/DDD system

The purpose of the ATC/DDD system is to serve as a tool for drug utilization monitoring and research in order to improve quality of drug use. One component of this is the presentation and comparison of drug consumption statistics at international and other levels.

A major aim of the Centre and Working Group is to maintain stable ATC codes and DDDs over time to allow trends in drug consumption to be studied without the complication of frequent changes to the system. There is a strong reluctance to make changes to classifications or DDDs where such changes are requested for reasons not directly related to drug consumption studies. For this reason the ATC/DDD system by itself is not suitable for guiding decisions about reimbursement, pricing and therapeutic substitution.

It is essential that a tool for drug utilization monitoring and research is able to cover most medicines available on the market. An important aim of drug utilization is to monitor rational as well as irrational drug use as an important step in improving the quality of drug use. **The classification of a substance in the ATC/DDD system is therefore not a recommendation for use and it does not imply any judgements about efficacy or relative efficacy of drugs and groups of drugs.**



Thank you

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