Informa Crop Protection Conference

OFF PATENT PRODUCTS AND GENERICS

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PARALLEL TRADE

From the Treaty of Rome to Article 52

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- The judicial construction of Europe
- Proportionality, consistency and legal certainty
- The single market for PPP and agricultural produce
- Public health and the protection of the environment
- Defining guidelines for Article 52

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Case 100/96 British Agrochem's legacy

20. **In the given circumstances,** the national court referred the following three questions to the ECJ for a preliminary ruling:

'1. **Does Directive 91/414/EEC** of 15 July 1991 as amended **allow a Member State to <u>permit</u> (!) the placing on the market** of a plant protection product imported from another EEA State or from a third country **because the Member State considers that product to be identical to a master plant protection product which has already been authorised by that Member State pursuant to Article 4(1) or 8(2) of the Directive**, when the imported product is deemed to be identical to the master product if:

(a) the active ingredient in the imported product is manufactured by the same company (or by an associated undertaking or under licence) as the active ingredient of the master product and is the same within variations accepted by the registration authority; and

(b) the formulation of the imported product is produced by the same company (or by an associated undertaking or under licence) as that of the master product and any differences in the nature, quality and quantity of the components are deemed by the registration authority to have no material effect on the safety of humans, domestic animals, livestock, wildlife or the environment generally or on efficacy?

Angela or Nicolas

- Who is running the show ?
  - Member States (and their charismatic leaders)
  - Council of ministers (+influential Competent Authorities)
  - Commission
  - Parliament
  - ECJ
  - National judges
  - Litigants
  - Big business

How did we get here ?

- 1958, integration is but wishful thinking
- 1966, Luxembourg Compromise tips the balance towards intergovernmentalism, Treaty provisions on QMV stand, yet unanimity becomes the norm, detrimental effect on decision making until the Single European Act takes effect in 1987.
- 1985, Delors' White Paper on the 'completion' of the **internal market**; specific commitment to **QMV**
- 1986, SEA brings environment policy into the Treaty; commits to cohesion policy; provides for EP's legislative role, **cooperation procedure**; target date 1992 !
- 1992, Maastricht Treaty; EU, **co-decision procedure**; introduction of the principle of **subsidiarity**

European Court of Justice

- Final arbitrator between EU institutions and Member States
- Ensures national compliance with EU Treaties

- Two decisions gave substance to the EU legal system :
  - Case Van Gend en Loos 1963, the Court establishes the doctrine of **direct effect**, mandates that EU citizens have the legal right to expect their governments to adhere to their European obligations
  - Case Costa v. ENEL 1964, **supremacy** of EU law over national law, in case of contradiction, the former prevails

Individuals can thus seek remedy for breaches of it through national courts

The process operates through the preliminary ruling system

European Court of Justice

The Court is a trustee of the Treaty, not an agent of national government.

The Treaty establishes the EC as a customs union,

Art. 26 prohibits MS from levying direct charges on goods traded across borders within the EC

Case 87/75 - Bresciani, has interpreted Art. 25 (Art. 30 TFEU) as capturing within its scope '**any pecuniary charge**', whatever its designation and mode of application, which is imposed on goods imported (*it does not say 'introduced'*) from another MS by reason of the fact that they cross a border. The Court would even stress that the Treaty does not here and elsewhere provide for exceptions or defence.

The free movement of goods provisions in the Treaty

Article 34 TFEU ex Article 28 TEC

Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.

Article 36 ex Article 30 TEC

The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. **Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.**

Case Law

The case law relating to the free movement of goods provisions in the TREATY as they affected integration and supranational governance

- **Case 8/74 – Dassonville**
  Constitutes a measure having an effect equivalent to a quantitative restriction as prohibited by the Treaty any national rule which, either directly or indirectly, adversely affect trade between Member States and consequently restrict competition.

- **Case 120/78 Cassis de Dijon**
  Not only measures, but also national administrations' practices, because they would have the practical effect of restricting imports, even though they did not directly target imported goods...

The Cassis de Dijon case further establishes the principle of '**mutual recognition**' :

A product made or sold legally in one MS cannot be barred in another MS through national standards …

- The principle is fundamental to the single market because it establishes that national variation in standards could exist as long as trade is not unduly impeded.
  On the other hand, a great many national measures indeed are capable of having an effect on the importation of goods !
- However the scope and full effect of this judgment was not completely apparent until the Commission used the principle as a cornerstone of its 1985 proposals to launch the single market
- Mutual recognition created a powerful incentive to harmonise

Case Law

- **Case 104/75 – De Pijper**
  National rules or practices do not fall within the exceptions specified in Art.30 if the health and life of humans can be effectively protected by measures which do not restrict intra-Community trade so much.

The Court declared that the MS could hardly claim to be acting in the interest of public health, if its policies discourage the distribution of lower costs medicines.

Finally the Court held that the various EC directives harmonising regulations of pharmaceuticals had no effect on the scope of Articles 28 and 30.

Consolidation of Dassonville-Cassis framework

- **Proportionality**: government may be allowed to restrict rights of individuals, but only to the extent necessary to achieve other socially beneficial goals

As seen at the time by MS and most observers beside the Court, the burden was on the plaintiff to show that a given measure had caused damaging effects on trade

- De Pijper ruling expanded Dassonville in ways that supports the need on both sides, MS and litigants, to engage in the style of argumentation developed in the pertinent case law ...

Zera / Montedison

93/554/EEC: Commission Decision of 22 June 1993

Farmoplant SpA,… Montedison … have infringed Article 85 of the EEC Treaty by participating, between the beginning of 1983 and the end of 1988, in an agreement under which Farmoplant and Montedison Deutschland undertook to afford Staehler **absolute territorial protection through product differentiation in respect of the plant protection product DIGERMIN, in order thereby to protect the German market against parallel imports from other Member States**.

Concerning Standards

- **Decision 3052/95/EC** of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community in non-harmonised sectors.

- Technical Standard and Regulation **Directive 98/34/EC** seeks to prevent the creation of new technical barriers to trade and lays down a procedure for the provision of information in the field of technical standards and regulations. *relevant to EEA and EFTA*

Heading for harmonisation from 49a to 52

- Yet the legislator stopped in midstream
- All agreed there was an issue
- Disagree on the real nature of the problem, common origin, repackaging, identity, …
- Refused to see the matter in its entirety
- Finally agreed on a minimal list of practicalities

They removed the stone in their shoe with a 45 days all in one approach.

The mandatory 45 working days conveniently justifies leaving out essentials like why doing the whole exercise in the first place, or its relevance to article 28 of the Treaty.

Heading for harmonisation from 34a to 52

- What if it is not identical ?
  - It is of no consequence to the single market ?
  - It is of no consequence to health and the environment for the rest of the EU ?
- The process is not transparent
- There is no recourse built in

How does that measure up against the Treaty ?

Directive 91/414/EEC recitals 5, 6 and 7

- Whereas, in view of the hazards, there are rules in most Member States governing the authorization of plant health products; whereas **these rules present differences which constitute barriers not only to trade in plant protection products but also to trade in plant products, and thereby directly affect the establishment and operation of the internal market**;
- Whereas **it is therefore desirable to eliminate such barriers by harmonizing the provisions laid down in the Member States**;
- Whereas uniform rules on the conditions and procedures for the authorization of plant protection products must be applied by the Member States;

Directive 91/414/EEC recitals 8 and 9

- Whereas such rules should provide that plant protection products should not be put on the market or used unless they have been officially authorized and should be used properly having regard to the principles of good plant protection practice and of integrated pest control;
- Whereas **the provisions governing authorization must ensure a high standard of protection, which, in particular, must prevent the authorization of plant protection products whose risks to health, groundwater and the environment and human and animal health should take priority over the objective of improving plant production**;

Regulation 1107 Article 52

1. **A plant protection product that is authorised in one Member State (Member State of origin) may, subject to granting a parallel trade permit, be introduced, placed on the market or used in another Member State** (Member State of introduction), if this Member State determines that the plant protection product is **identical** in composition to a plant protection product already authorised in its territory (reference product). The application shall be submitted to the competent authority of the Member State of introduction.

2 …

Regulation 1107 Article 52

3. Plant protection products shall be considered as identical to the reference products if:

(a) they have been manufactured by the same company or by an associated undertaking or under licence in accordance with the same manufacturing process;

(b) they are **identical** in specification and content to the active substances, safeners and synergists, and in the type of formulation; and

(c) they are either the same or equivalent in the co-formulants present and the packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.

Identity : The Crunch

The most famous sentence from 'British Agrochemicals' : '…***if not identical in all respects to a product already authorised within the Member State of importation, at least shares …'***

In Article 52 there are cumulative requirements

Chose but one, the weakest, most obvious, and you need not investigate the application any further

Such rigid a notion of identity can lead to excesses which in the absence of transparency and means of recourse fall outside the free movement of goods provisions in the Treaty

Identity, conversely

Art. 52 does not define what is :

…due regard to differences which may exist in conditions relating to agriculture, plant health and environment, and in particular climatic conditions, relevant to the use of the product,

or pricisely what is *common origin*

or criteria for over-labelling of parallel traded PPP so as to shield traders from trademarks litigations

In brief, it leaves plenty of scope

for MS to make abusive use of article 30 (36TFEU) and

for big business to litigate against parallel traders

Critically left opened:

- Producer responsibility, product liability, product defect, phytotoxicity, …, and the responsibility of the holder of the PTP;
- Prohibitive Costs of PTP;
- Imports by farmers for their own use;
- Safety Data Sheets, translation of the MSDS for the product of import or use of the MSDS for the product of reference with or without the originator's name and details ?

Critically left opened:

- Rules for labelling, re-labelling or over-labelling; potential coexistence of conflicting uses or conditions of use in the same language;
- trademarks, **C-348/04;**
- Obligation on the part of farmers and distributors to ensure they are buying a PPP holding a valid MA, use of official data bases on the Internet, law suits for copyrights and/or trademark infringement;
- Criteria for authorising complete repackaging of PT PPP.

PTP v MA

- The Council's lawyers' definitions :
  - **Approval** in case of the positive list of active substances
  - **Autorisation** when placing a plant protection product on the market
  - **Permit** for trials and parallel trade

Sophism ?

Do you think it possible to accept an application for a parallel trade of a product that in the country of origin has already been put on the market under the parallel trade permit provisions (parallel trade of a parallel trade) ?

No. Article 28 – 1. of 1107/2009 makes it clear that a "plant protection product shall not be placed on the market or used unless it has been authorised in the Member State concerned in accordance with this Regulation". Article 28 goes on to establish a number of derogation's to this including under Article 28 – 2.(e) that a no authorisation shall be required "when placing on the market and use of plant protection products for which a parallel trade permit has been granted in accordance with Article 52"

Sophism ?

It follows that a parallel trade permit is not an “authorisation” for the purposes of the regulation. Article 52 – 1. makes clear “A plant protection product that is **authorised** in one Member State (of origin) may, subject to granting a parallel trade permit, be introduced, placed on the market or used in another Member State”.

Therefore only authorised plant protection products may be granted a parallel import permit and as parallel imports themselves do not have such an authorisation a parallel permit may not be granted on a product which is itself a parallel.

Case 100/96 British Agrochemicals

Judgment

36. If, on completion of the examination carried out by the competent authority of the Member State of importation, the latter finds that all the abovementioned criteria are fulfilled, the plant protection product to be imported must be considered to have already been placed on the market of the Member State of importation and, accordingly, must be able to **benefit from the marketing authorisation** granted in respect of the plant protection product already on the market, unless that is precluded by considerations concerning the effective protection of human and animal health and of the environment.

40. *again*

Operative part of the judgment *repeated*

Case Study

A company's PI PPPs sold in Denmark	The reference PPPs as registered in Denmark
HERBASAN (reg. 18-452) Content : 160g/l phenmedipham	**(reg. 18-528)** Content : 160g/l phenmedipham
ETHOSAN SC (reg. 18-451) Content : 500g/l ethofumesate	**(reg. 18-426)** Content : 500g/l ethofumesate

In Conclusion

Considering all PPP are authorised in every MS after satisfying all conditions laid down in the directive or the Regulation,

and further considering the free movement of agricultural produce and people,

it is absurd to subject, in these conditions, intra community traded PPP to MA or PTP notably with a national test of identity,

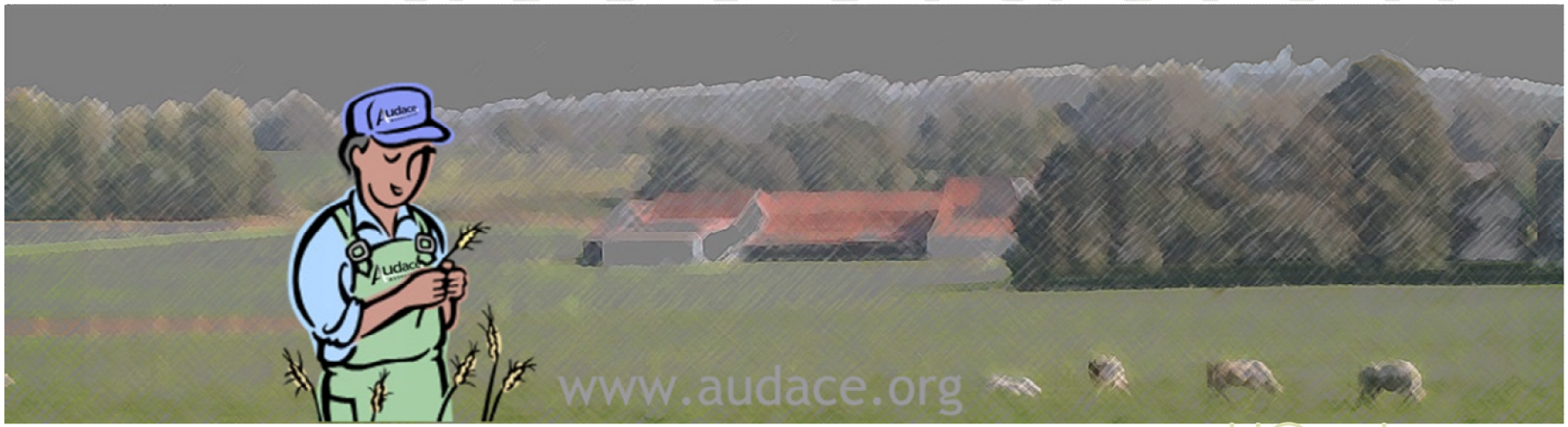
all the more so within parts of the EU where mutual recognition is made compulsory.

However, a sophism is being nurtured according to which these grey products evolving in a grey market are of a lower status, undesirable, unethical, detrimental to innovation and even simply counterfeit.

In Praise of Parallel Trade

- Parallel trade is too often seen as mercantile, predatory and detrimental to research capacity of R&D companies.

- As a matter of facts, besides being the watch dog of price and competition, parallel trade could also win its titles of nobility from being the means by which a safer ‘truly single’ market for PPP is eventually achieved.



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