JUDGMENT no. *738*

THE EXAMINING DIVISION AT THE COURT OF APPEAL OF RENNES

November 13th, 2003

LORIENT

X.
ASSISTED WITNESSES
ERNETA, Francisco Javier
REVILLANT, Inaki
Civil parties
Regional council of the order of veterinary surgeons of Brittany and four others

Importing veterinary drugs without a licence etc.

UPHOLDING ORDER NOT TO PROCEED

HEARING OF NOVEMBER THIRTIETH, TWO THOUSAND AND THREE

THE EXAMINING DIVISION OF THE COURT OF APPEAL, RENNES, sitting in chambers and assembled as stated below, gives judgment as follows:

See the proceedings instituted before the *tribunal de grande instance* [civil and criminal court of first instance] of LORIENT:

X.

For: **importing veterinary drugs without authorisation, administering the same to animals intended for human consumption or unlawfully holding substances or preparations without a licence under the regulations on veterinary drugs and substances intended for animal consumption, trading in dangerous substances presented in such a way as to render them liable to be confused with foodstuffs:**

ASSISTED WITNESSES:

REVILLA Inaki
born SAN SEBASTIAN, SPAIN, September 30th, 1966
Spanish nationality

ERNETA, Francisco-Javier
Born PAMPLUNA, SPAIN, on January 6th, 1962
Electing address for service at Me MONTENOT – 7, avenue Niel, 75017 PARIS

CIVIL PARTIES:

REGIONAL COUNCIL OF VETERINARY SURGEONS OF BRITTANY
23, rue Lesage, 35000 RENNES
Having as counsel Me YVON, of 2, rue Duplaix, 56100 LORIENT, Me DECHEZLEPRETRE, of 53, rue Cardinet, 75017 PARIS

HIGHER COUNCIL OF THE ORDER OF VETERINARY SURGEONS
34, rue BREGUET, 75011 PARIS
Having as counsel Me YVON, of 2, rue Duplaix, 56100 LORIENT, Me DECHEZLEPRETRE, of 53, rue Cardinet, 75017 PARIS

VETERINARY AND REACTIVE DRUG INDUSTRY ASSOCIATION

Having as counsel Me Pierre, of 38, avenue Gambetta, 56100 LORIENT, Me TISSEYRE-BONNET, of 5, rue Lincoln, 75008 PARIS

NATIONAL ASSOCIATION OF INDEPENDENT VETERINARY SURGEONS
10, place Leon Blum, 75011 PARIS
Having as counsel Me YVON, of 2, rue Duplaix, 56100 LORIENT, Me DECHEZLEPRETRE, of 53, rue Cardinet, 75017 PARIS

FEDERAL CONSUMERS' UNION "QUE CHOISIR"
of 11, rue Guénet, 75011 PARIS

Having regard to the order not to proceed given on March 14th, 2003, by the examining magistrate of the *Tribunal de Grande Instance* of LORIENT, and notified the same day to the civil parties and their counsel and to the assisted witnesses and their counsel;

Having regard to the appeal lodged with the office of the clerk of the *Tribunal de Grande Instance*, LORIENT:

- On March 18th 2003 by Maitre YVON acting on behalf of Maitre DECHEZLEPRETRE on behalf of
  - The higher council of the order of veterinary surgeons
  - The national association of independent veterinary surgeons
  - The regional council of the order of Brittany veterinary surgeons

- On March 19th 2003, by Maitre Lucie PIERRE, standing in for Maitre Simon BRUNET, on behalf of the national federation of consumers QUE CHOISIR

- On March 20th 2003, by Maitre Lucie PIERRE, standing in for Maitre TISSEYRE-BONNET, on behalf of the veterinary and reactive drug industry association

The file containing the public prosecutor's charges was lodged with the clerk of the examining division on September 12th 2003.

Having regard to the opinions sent by registered mail on September 12th, 2003, by the public prosecutor to the civil parties and their counsel and to the assisted witnesses and their counsel, informing them that the procedural file would be considered by the examining division at the hearing of Thursday, October 2nd, 2003, at 09.00.

Having regard to the memoranda lodged with the office of the clerk of the examining division:

– On September 29th 2003, at 09.00, by counsel for the assisted witnesses

– On September 30th 2003, at 16.00, by counsel for the veterinary and reactive drug industry association, civil party to the proceedings

– On October 1st 2003, at 09.00, by counsel for the higher council of the order of veterinary surgeons, the regional council of the order of veterinary surgeons of Brittany and the national association of independent veterinary surgeons;

Having regard to the other documents in the case.

At the hearing of October 2nd, 2003, in chambers, having heard:

Monsieur GIMONET, judge's report

Monsieur VANNIER, general deputy, in his oral pleadings

Maitre DECHEZLEPRETRE, counsel for the higher council of the order of veterinary surgeons, the regional council of the order of veterinary surgeons of Brittany and the national association of independent veterinary surgeons, civil parties, in his pleadings

Maitres LEBRAS and TISSEYRE-BONNET, counsel for the veterinary and reactive drug industry association in their pleadings

Maitre MONTENOT, counsel for the assisted witnesses, in his pleadings, and having heard the latter.

Judgment was deferred to be given at the hearing on November 13th, 2003

And on that day, November 13th, 2003, having considered in accordance with Article 200 of the criminal procedural code, in the absence of the public prosecutor and the clerk, sitting as composed

Having regard to Articles 186, 207 paragraph 3 and 502 of the Criminal Procedural Code,

Whereas, by way of introduction, pleadings were lodged on the day of the hearing by the ALBAITARIZA company and the association of Breton growers claiming, under Article 41 of the law of July 29th, 1881, that two paragraphs of the memorandum of the higher council and regional council of he order of veterinary surgeons, which they claimed were libellous, should be removed, and that they be reserved the right to bring a civil action;

But whereas those pleadings were made in the name of persons not party to the proceedings, and were not signed;

And whereas they must therefore be ruled inadmissible;

Whereas the appeals were brought within the time allowed and are admissible;

Whereas the facts of the case as established are as follows:

On June 10th 2001, the inspectors of the BNVS informed the public prosecutor's office of LORIENT that Spanish veterinary drugs were being unlawfully imported and used main by poultry and dairy farmers within the jurisdiction of the *Tribunal de Grande Instance* of LORIENT;

That the drugs in question were as follows:

- Quinoex 10, enroflaxaxine based, an antibiotic included in List I of poisonous substances
- Maylosina, tilosine-based, an antibiotic included in List I of poisonous substances
-
- Hipramin B, based on amino acids and vitamins.

These products were made in Spain, and came from the Spanish company ALBAITARITZA, being transported to Brittany by haulage contractors, the company TPE.

They were not imported under a licence issued by the French food safety authority AFSSA nor a marketing licence (AMM) as required under Articles 5141-5 and 5142-7 of the Code of public health.

It appeared that the ALBAITARITZA company had supplied a hundred or so poultry breeders, distributed over the *departments* of Morbihan, Finistere, the Cotes d'Armor, the Landes, Lot and Pyrenees Atlantiques since the start of 2001, with an estimated eight tonnes.

On July 6th 2001, following information from the carrier, TFE, the gendarmes of PONTIVY and the inspectors of the BNVS were called in at MESLAN (56) to premises where 80 kilos of antibiotic drugs were being delivered, labelled as 'foodstuffs', intended for cattle breeding.

The managers at GABC admitted taking supplies from the Spanish company, which was offering prices much lower than those in France. They said the agent for the ALBAITARITZA company was called Jean-Yves PAUL, and lived at BERRIEN (29).

On July 10th 2001, investigations were opened against persons unknown for importing veterinary drugs without authorisation, giving them to animals intended for human consumption and unlawfully keeping substances or preparations without a licence under the regulations on veterinary drugs and substances intended for animal consumption, trading in dangerous substances presented in such a way as to render them liable to be confused with foodstuffs.

The veterinary and reactive drug industry association (SIMV) and the regional council of the association of Brittany veterinary surgeons, the national association of independent veterinary surgeons and the higher council of the order of veterinary surgeons joined themselves as civil parties, as did the association UFC "Que Choisir".

The SIMV stated that, as far as veterinary drugs were concerned, the rule was that an import licence had to be obtained first, wherever drugs came from, that licence being issued by the French food safety agency, AFSSA.

All veterinary drugs also have to have a marketing licence issued (AMM).

The European association of agrochemical users and distributors, AUDACE, wrote to the examining magistrate. Heard under rogatory commission, its Chairman, Daniel ROQUES, said that its members, parallel importers, were operators who, under the principle of free movement of goods under Article 28 of the Treaty of Europe, took their supplies from wholesalers or retailers of countries of origin at prices less than the exclusive brand networks.

He stressed that the major brands could call on exclusive distribution networks, which, having taken the necessary formalities, controlled prices and intended to keep it that way. He claimed only parallel imports were the only way of fighting the distribution monopoly of the major brands and creating a free market.

He added that the Court of Justice of the European Communities (ECJ) had spoken out against unjustified obstacles to parallel imports, especially pharmaceutical and phytopharmaceutical products, which were subject to the same national and international rules as those of veterinary drugs.

If, he claimed, an imported product had a marketing licence in its country of origin but was otherwise similar to a reference product which itself had a marketing licence in France, the provisions of the directive on procedures for issuing marketing licences did not apply here, as this would be contrary to the principle of the free movement of goods as laid down by Article 28 of the Treaty.

All that was required was to verify that the two products originated from a common source, that, without being identical on all counts, they had to be made according to the same formula, using the same active agent and have the same effects, which the importing Member State could verify by consulting the product manufacturer or the competent authorities in the Member State of origin.

It appeared from the examination of growers who had bought veterinary drugs from the ALBAITARITZA company that poultry breeders were aware of that company's existence via trade meetings and word of mouth. Orders were given by telephone, then confirmed by fax, and sent by carrier within 15 days (very often by TFE), accompanied by an order. Veterinary surgeons from the Spanish company visited the operations fairly frequently.

The breeders said that the ALBAITARITZA company sold the drugs much more cheaply (up to five times more cheaply) than similar drugs available in France. It emerged that, generally, poultry breeders completed health files stating the drugs used in detail.

Inaki REVILLA, Chairman and CEO of the company ALBAITARITZA, and Francisco Javier ERNETA, veterinary surgeon, were heard by the examining magistrate as assisted witnesses.

ERNETA produced lists of products exported to France: he stated that all these products had marketing licences in SPAIN, and had corresponding equivalent products in FRANCE which themselves had marketing licences in FRANCE.

For each drug, ERNETA gave the name of the laboratory in France making the equivalent product. Some products were made then bought in FRANCE and resold in FRANCE by ALBAITARITZA.

All drugs shipped to FRANCE were accompanied by instructions in three languages (French, Basque and Spanish). These instructions gave the waiting times for each veterinary product, that is, the periods of time during which, once they were administered via animals, no meat, milk or eggs from those animals could be sold to prevent drug molecules from getting into human food.

ERNETA explained the differences between the prices used in FRANCE and SPAIN by the differences in distribution systems, as veterinary surgeons had a monopoly over distributing drugs in France, and refused to issue prescriptions without selling the drugs concerned, distributed by four purchasing centres, which did not exist in SPAIN.

As to the waybill from the haulage company TFE, bearing the words 'foodstuffs', Inaki REVILLA stated that these words might have been added by the carriers themselves and that, in any case, there was nothing to gain by putting incorrect statements on VAT returns.

ON IMPORTING VETERINARY DRUGS WITHOUT AUTHORISATION AND ADMINISTERING THEM TO ANIMALS INTENDED FOR HUMAN CONSUMPTION

Under the terms of Article 28 of the Treaty establishing the European Economic Community, quantitative import restrictions and any measures of equivalent effect are prohibited between Member States.

It is true that Article 30 of the Treaty provides that the provisions of Article 28 cannot be invoked against import prohibitions or restrictions justified on grounds of protecting the health and life of persons and animals, but provided nonetheless that those prohibitions or restrictions do not amount to 'either a means of arbitrary discrimination nor disguised restrictions on commerce between Member States'.

It is thus that, by decree of July 11th 1974 (Crown Prosecutor v. Dassonville), the Court of Justice of the Economic Communities, ruling on the application of national legislation on appellation of origins, said that a measure of equivalent effect to quantitative restrictions included 'any commercial regulations in Member States which was liable to undermine intra-Community trade, either directly or indirectly, actually or potentially'.

If no marketing licence exists for a drug in the Community, it cannot be imported into France without first holding a marketing licence [AMM] procedure involving tests and scientific analysis.

Parallel imports are a different situation: here, the product imported has a marketing licence in its country of origin, but is otherwise similar to a reference product for which a marketing licence exists in the country of importation.

The Court of Justice of the European Communities was led to pronounce on this latter hypothesis in respect of parallel imports of phytopharmaceutical specialities, thus setting principles transferable to veterinary specialities, in terms of a common imperative of protecting public health.

By order of March 11th, 1999 (ref. C 100/96) on a phyto-pharmaceutical product, the Court of Justice of the European Communities ruled in law that:

"If the competent authorities in a Member State conclude that a phytopharmaceutical product imported from a State in the European Economic Area in which it already holds a marketing licence issued pursuant to Directive 91/414/EEC of the Council of 15 July 1991 on the marketing of phyto-pharmaceutical products, without being entirely identical on all counts to a product already licensed in the territory of the importing Member State unless

- *It has a common origin with that product in that it was made by the same company or an associated company or working under licence to the same formula,*

- *It was made using the same active agent, and*

- *It also has the same effect, allowing for the differences which may exist in terms of agricultural, phytosanitary and environmental conditions and climate conditions in particular affecting the use of the product*

that product must be considered, unless considerations of protection of human and animal health and those of the environment would indicate otherwise, capable of enjoying the marketing licence already granted in the importing Member State".

In giving its judgment, the Court of Justice of the European Communities recalled that it had previously found, in its judgment of November 12th, 1996 (case of Smith and Nephew v. Primecrown) that Directive 65/65 on issuing marketing licences *"could not apply to a pharmaceutical speciality for which a marketing licence exists in a Member State and importing which into another Member State amounts to parallel imports compared with a pharmaceutical speciality for which a marketing licence already exists in that second Member State, on the grounds that, in that event, that imported speciality cannot be considered as being brought onto the market in the importing Member State for the first time,"* adding that *"the competent authorities of the importing Member State must verify that both pharmaceutical specialities, which are of common origin in that they were made further to agreements made with the same licensor, were, without being identical on all counts, nonetheless made using the same formula and using the same active agent and having the same therapeutic effects."*

It therefore appears that verifying the similarity of imported products for which a marketing licence exists in the Member State of origin with other products for which marketing licences exist in France must be done using a simplified licensing procedure.

Demanding, on the other hand, that such foreign products be subjected to the marketing licence procedure in France, involving tests and scientific analysis, would be tantamount to undermining intra-Community trade.

It appears from the documents furnished by the ALBAITARITZA company that the veterinary drugs which it is liable to import into FRANCE have undergone a marketing licence procedure in SPAIN, and that they all have equivalents in FRANCE for which marketing licences exist.

The drug companies which have attached themselves as civil parties to the proceedings stated, in a memorandum to the examining magistrate of January 7th, 2002, that they were going to study the list of drugs at issue distributed by the ALBAITARITZA company, stating that they 'believed they had acquired a certain skill in identifying' those products, even if they thought a representative of the AFSSA could be heard.

Under the terms of their memorandum, those drug companies are only actually disputing four drugs on that comparative list: COFALYSOR 250 ml, DOXI-10 SP which the SOGEVAL company claims is not equivalent to the French product DOXIVAL, INTRAMICINE and SACHET REPAS [food sachet].

On the other hand, it does not appear that any of those four products appears amongst the products or on the orders, invoices or waybills which the gendarmes seized from the growers as a whole.

There is therefore no evidence that these products have been imported into France.

As these products have undergone marketing licence procedures in SPAIN and have equivalents which have themselves undergone marketing licence procedures in FRANCE, they cannot be subjected, as has been stated, to a marketing licence procedure, which would amount to, if not a disproportionate measure obstructing the free movement of goods, then a measure of equivalent effect to a quantitative restriction on imports for the purposes of the Treaty.

Now, France does not have any simplified licensing procedures which could be applied to parallel imports for marketing veterinary drugs.

These circumstances come under Article L 5141-5 of the Code of public health, according to which any veterinary drug for which there is no marketing licence issued by the competent authorities of the European Community must, prior to being marketed, undergo marketing licence procedures for licences issued by the French food safety agency.

In a Ministerial reply of October 29th, 2001, the Minister of Agriculture and Fisheries stated that, when it came to veterinary drugs licensed in other countries of the European Union having access to the French market, the European Commission thought that French legislation should be completed in terms of Article 28 of the Treaty to enable veterinary drugs to circulate more easily within the European Union. The Minister stated that a draft French decree had 'been drawn up to facilitate these so-called 'parallel' imports of veterinary drugs, using a simplified procedure'.

The representatives of the ALBAITARITZA company cannot justly be accused of not having produced licences for the products at issue as no simplified approval procedure exists in France as yet, and any application they might have made could not have been met under the law as it stands.

As European legal standards take precedence over national ones here, the courts must apply the provisions of Community law directly, even though national law indicates otherwise.

It is therefore up to the courts hearing the case to dismiss the application of incriminating national law if it clearly appears that the latter ignores the existence of the provisions of the Treaty establishing the European Economic Community or legislation passed implementing it.

The fact that France does not have a simplified licensing procedure for marketing veterinary drugs does not make it a crime to treat animals intended for human consumption or keeping without a licence substances or preparations for which no marketing licences have been issued by AFSSA on the part of the ALBAITARITZA company or growers who acquired products without a licence the importation of which cannot be subjected to marketing licence procedures without flouting the provisions of Article 28 of the Treaty.

Moreover, and under the provisions of Article L 5142-7 of the Code of public health, importing veterinary drugs is subject to licence by the French food safety authority, a marketing licence as provided for under Article L 5141-5 constituting a marketing licence.

It follows that, even with parallel imports, French law still requires a marketing licence, as AFSSA cannot issue marketing licences directly and certainly not where there are health issues involved.

Such requirements are contrary to European law.

In the absence of any simplified licensing procedure, it would appear impossible to charge the ALBAITARITZA company with without a licence imports or the growers with acquiring products without a licence where the products could not have been subjected to marketing licence procedures without flouting the provisions of Article 28 of the Treaty.

Lastly, Article L 5142-7 also provides that no import licence is required for drugs made in another Member State, but states that such drugs must be accompanied by a certificate the contents of which are laid down by the decree provided for in section 15 of Article L 5141-16.

No such decree has actually appeared to date, so that no-one can be accused of importing anything without a certificate.

ON MARKETING SUBSTANCES OR PREPARATIONS UNDER A PRESENTATION OR NAME LIABLE TO CAUSE CONFUSION WITH FOODSTUFFS

Under the provisions of Article R 5154 of the Code of public health, no substances or preparations as laid down in Article R 5152 may be made or marketed, that is, carried, imported, exported, kept, offered, assigned or acquired in a presentation or under a name liable to create confusion with a foodstuff, drug, cosmetic or physical hygiene product.

It is true that the waybills seized from the TFE company carried the words 'foodstuffs', together with the word 'fresh' in some cases. Some documents accompanying the waybill also appeared to be specific instructions from the shippers, according to which the products had to be kept at a temperature of between 2 °C and 4 °C at all times during transport.

The operating manager of the haulage company TFE "Landes-Pyrenees" also explained that the words 'foodstuffs' appeared systematically on waybills and by default on all TFE national haulage waybills.

TFE's manager in SPAIN added that these words appeared only on bills for French agencies, and not on international waybills (CMRs) issued in SPAIN.

It also appears that, if the carrier was other than TFE, the waybill made out in Spanish also referred specifically to 'productos veterinarios'.

Whatever the words used on the haulage documents, in fact, it appears clear that, as far as the process of sale, packing marks and presentation of the veterinary products at issue, any risk of confusion with any food or cosmetic product was manifestly impossible.

In fact, these sales were made at meetings of animal breeders, following an order from one of those breeders, and accompanied by instructions issued by a veterinary surgeon in quantities and packing which made it obvious that the product was not intended for human consumption.

Whereas the investigations have not produced sufficient evidence to indicate the offences listed on the original charge sheet, or any other offence falling within the jurisdiction of the examining magistrate such as those claimed in the memoranda from the higher council of the association of veterinary surgeons, the regional council of the order of veterinary surgeons of Brittany, the national association of independent veterinary surgeons or the veterinary and reactive drugs industry association, given that no further charges have been brought;

That there does not appear to be any point in ordering any further investigations;

That, under these circumstances, the order should be upheld as issued;

FOR THESE REASONS

The Court

Rules the pleadings lodged on behalf of the ALBAITARITZA company and the association of Breton growers inadmissible;

Upholds the order not to prosecute issued by the examining magistrate of the *tribunal de grande instance* of LORIENT on March 14th, 2003;

Orders all goods seized to be restored;

Orders that the present judgment be notified and served in accordance with the formalities required under Article 217 of the criminal procedural code;

Given at the Court Buildings, Rennes, on November the thirteenth, two thousand and three, in chambers, sitting in the persons of Monsieur BAILHACHE, acting chairman, Madame TURBE-BION and Monsieur GIMONET, judges, all three duly appointed under Article 191 of the criminal procedural code,

In the presence of Monsieur VANNIER, deputy general

The present judgment being signed by the Chairman and Jocelyne FILLODEAU, Clerk of the Court, present at the hearing

THE CLERK	THE CHAIRMAN
(signed)	*(signed)*