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LUNDBECK AND THE DEATH PENALTY: Q&A legal briefing for shareholders

Lundbeck's product pentobarbital is increasingly being used in a new procedure to execute prisoners in the USA. Lundbeck's management recently decided against imposing 'end-user agreements' designed to prevent this unauthorised use. This briefing explains the legal issues involved.

1) Background

Recent shortages of the anaesthetic sodium thiopental have forced prisons in Oklahoma, Ohio and Texas to abandon the standard lethal injection protocol used by the majority of executing states and switch to pentobarbital – an untested alternative. Mississippi and Arizona have also stated their intention to switch to pentobarbital, and it can only be a matter of time before other executing states follow suit.

As the only licensed supplier of pentobarbital in the United States, Lundbeck has the power to halt countless executions by putting in place 'end-user agreements' with its customers. Such agreements would stop intermediaries selling Lundbeck's chemicals on to state penitentiaries.

By choosing not to put these measures in place, the company has opened its doors to doing business with executioners all over the USA. Lundbeck's decision will also encourage more executing states to adopt pentobarbital for use in executions. Such a use is considered experimental because the drug, a sedative, was not designed for executions and has no clinical history of such use.

2) What is pentobarbital?

Pentobarbital is a short-acting barbiturate used in animal euthanasia and for a number of therapeutic purposes in humans, including the treatment of seizures and preoperative sedation. Since December it has been used in executions by lethal injection in the United States, despite the fact that it is not FDA-approved for this use.

According to Dr. David Waisel, Associate Professor of Anaesthesia at Harvard Medical School: *"The use of pentobarbital as an agent to induce anesthesia has no clinical history and is non-standard... the combination of significant unknowns... puts the inmate at risk of serious undue pain and suffering."*

3) What is Lundbeck's involvement?

Lundbeck is the only supplier of pentobarbital in the US. This means that every gram of the chemical that ends up in the veins of a condemned prisoner is manufactured by Lundbeck. Lundbeck previously considered the possibility of putting in place 'end-user agreements' that would have prevented their products being sold to state

penitentiaries for execution purposes. However, on 25th March 2011 Lundbeck's management decided not to take this action.

4) What is Lundbeck's legal situation?

As signatory to the European Convention on Human Rights (ECHR), Denmark has pledged her active commitment to the abolition of the death penalty (See *Article 1, Thirteenth Protocol to the ECHR*). Lundbeck's current material support for executions is therefore in violation of the Danish government's obligations under international law. Imposing 'end-user' agreements would bring Lundbeck a step closer to full compliance with the ECHR.

5) Can Lundbeck legally impose 'end user' contracts on its distributors?

Yes. Lundbeck's contractual relationships with distributors are governed by US law. 'End-user agreements' dictating that a purchaser may not use the purchased product in certain ways are not unusual in US contract law.

Private parties are free to enter into contracts of all kinds, including contracts with restrictive clauses. The law will enforce clauses that restrict a purchaser's freedom to distribute a product, so long as the restriction is reasonable and does not conflict with public policy (discussed below).

Relevant legal precedents

- *Twin City Pipe Line Co. v. Harding Glass Co.*, 283 U.S. 353, 356 (1931) ("The general rule is that competent persons shall have the utmost liberty of contracting and that their agreements voluntarily and fairly made shall be held valid and enforced in the courts.")
- *Harris v. Walker*, 519 N.E. 2d 917, 919 (Ill. 1988) ("Public policy strongly favors freedom to contract, as is manifest in both the United States Constitution and our constitution.")
- *Garza v. Chicago Health Clubs, Inc.*, 329 F. Supp. 936, 940 ("Negative covenants are as valid and enforceable...as other kinds of contract terms assuming that they do not violate the public policy of the State.")

6) Is it reasonable for Lundbeck to impose 'end-user' contracts?

Yes. There are three main rules here:

a) The restriction must not be broader than necessary for the protection of the seller's legitimate interests. In Lundbeck's case, a restriction on the sale or use of pentobarbital in lethal injections would be as tailored as possible to protect the company's interests, and thus the first hurdle is easily overcome.

b) The restriction must not have an excessively onerous effect on the purchaser. The effect on Lundbeck's distributors would be slight, as the sale of pentobarbital for lethal injections represents a small fraction of its overall use in the market, and likely constitutes a negligible portion of the distributors' overall business.

c) The restriction must not have a negative impact upon the public welfare or common good. Discussed below.

Relevant legal precedents

- *Cosmetic Gallery, Inc. v. Schoeneman Corp.*, 495 F.3d 46 (3rd Cir. 2007) (upholding stringent restrictions placed upon hair-care product distributors by their manufacturers)
- *Maris Dist. Co. v. Anheuser-Busch, Inc.*, 302 F.3d 1207 (11th Cir. 2002) (upholding Anheuser-Busch's contractual right to approve any change in ownership of its distributors)

7) Would imposing 'end user' contracts affect public welfare or the common good?

No. The US Supreme Court has long held that public policy is to be ascertained by reference to statutes and legal precedents. 'Public policy' is thus synonymous with the laws of the state or country, and promises which are not illegal do not violate it.

As there is no constitutional, legislative or judicial imperative mandating that lethal injection drugs be made widely available, or that pentobarbital be made available in capital punishment, it is extremely unlikely that the clause would be invalidated on that basis.

Recent law has reframed the issue of public policy in terms of competition, so that restrictions are unenforceable on grounds of public policy if they are unreasonable in restraint of trade. The federal Sherman Act prohibits "*every contract, combination..., or conspiracy, in restraint of trade or commerce*". However, for vertical restrictions like end-user agreements, the courts analyze contracts under the 'rule of reason' standard – weighing *all* the circumstances in deciding whether or not an *unreasonable* restraint of trade has occurred. This includes the intention and purpose behind the restriction.

Any restriction put in place by Lundbeck on the use of its pentobarbital in executions would not be aimed at subverting competition, nor is it likely to do so. Rather, the company's aim is to avoid use of the product that may subject the company to legal consequences in Denmark or elsewhere, and that has the potential for serious harm to its public image and goodwill.

Under these circumstances, a reviewing court would likely hold that the proposed restriction passes the 'rule of reason' test and Lundbeck should be able to legally contract with its distributors to restrict sales of the drug.

Relevant legal precedents

- *O'Hara v. Ahlgren, Blumenfeld and Kempster*, 537 N.E.2d 730, 734 (Ill. 1989) ("The public policy of this State is reflected in its constitution, its statutes and its judicial decisions.")
- *Mohanty v. St. John Heart Clinic*, S.C., 866 N.E.2d 85, 92–93 (Ill. 2006) (discussing the "heavy burden" faced by those seeking to declare a contract provision void as against public policy)
- *American Needle, Inc. v. National Football League*, 130 S.Ct. 2201, 2208 (2010) (the Sherman Act is not nearly so broad in application as its language might suggest)
- *Continental T. V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36 (1977).

- *Board of Trade of City of Chicago v. U.S.*, 246 U.S. 231, 238 (1918) (“The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition...The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts [in determining legality]”)

8) What happens if the ‘end user’ agreement is breached?

A number of remedies are available to Lundbeck in the event that a distributor breaches a distribution agreement with the company.

Rescission (termination of the contract) is generally available as a remedy for *material* breach but this can be unduly burdensome on both parties. Actual damages are available for a material breach, but may be difficult to determine where the loss is to a company’s brand or goodwill. A contractual clause fixing liquidated damages (the type awarded when actual damages are difficult or impossible to determine, e.g. when a trade secret is disclosed) raises none of these issues.

The factors determining whether or not a breach will be considered *material* are:

- a) The extent to which the victim of the breach was deprived of a reasonably-expected benefit.
- b) The extent to which the victim of the breach can be adequately compensated for the part of the benefit that will be lost.
- c) The extent to which the party in breach will suffer forfeiture.
- d) The likelihood of the party in breach curing its own failure.
- e) The extent to which the behaviour of the party in breach complies with standards of good faith and fair dealing.

A distributor’s breach here may subject Lundbeck to liability in Denmark or elsewhere, and has the potential for highly negative publicity and loss of goodwill for the company, which should satisfy the materiality element. If doubt remains, the company may include express language in the contract declaring that breach of the distribution restriction is inherently material.

Relevant legal precedents

- *Mohanty v. St. John Heart Clinic, S.C.*, 866 N.E.2d 85, 95 (Ill. 2006) (rescission available as remedy for material breach)
- *Prima Tek II, L.L.C. v. Klerk’s Plastic Industries, B.V.*, 525 F.3d 533, 538-539 (7th Cir. 2008) (discusses the factors taken into account when determining materiality)
- *In re Krueger*, 192 F.3d 733, 742 (7th Cir. 1999) (parties may insert contract terms declaring certain breaches to be inherently material)
- *Dunkin’ Donuts of America, Inc. v. Middletown Donut Corp.*, 495 A.2d 66, 75 (N.J. 1985)
- *Jameson Realty Group v. Kostiner*, 813 N.E.2d 1124, 1130 (Ill. App. Ct. 2004) (discusses the circumstances in which the court will approve liquidated damages)

9) Can Lundbeck impose an agreement under patent instead?

We have not yet been able to determine the exact scope and coverage of Lundbeck's patents on pentobarbital. However, if the company is in possession of sufficient patents to grant them exclusionary rights on pentobarbital, the analysis is even simpler. For patented products, the ability to restrict the use or distribution of the product is part of the exclusionary grant given by the patent. Lundbeck would have the right to specify that their drugs were not to be used to kill prisoners, and a violation of that agreement would be considered patent infringement.

Relevant legal precedents

- *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 703 (Fed. Cir. 1992)
- *General Talking Pictures Corporation v. Western Electric Co.*, 305 U.S. 124, 127 (1938)
- *Pioneer Hi-Bred Intern., Inc. v. Ottawa Plant Food, Inc.*, 283 F.Supp.2d 1018 (N.D. Iowa 2003).
- *E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70, 89 (1902) ("the rule is, with few exceptions, that any conditions which are not in their very nature illegal with regard to this kind of property, imposed by the patentee and agreed to by the licensee for the right to manufacture or use or sell the article, will be upheld by the courts")

10) Summary of legal position

Lundbeck may restrict its distributor or end-use agreements, forbidding the sale of pentobarbital for use in capital punishment. The restrictions are unlikely to be held in violation of anti-trust laws or public policy, and rescission, liquidated damages, or actual damages will be enforceable upon breach.

Reprieve
PO Box 52742
London EC4P 4WS
Tel: 020 7353 4640
Fax: 020 7353 4641
Email: info@reprieve.org.uk
Website: www.reprieve.org.uk

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