

1 Roxane Laboratories, Inc., Appellant, v. Tracy, Tax Commr., Appellee.

2 [Cite as Roxane Laboratories, Inc. v. Tracy (1996), ___ Ohio St.3d ____.]

3 *Taxation -- Sales and use taxes -- Equipment used to perform Federal*
4 *Food and Drug Administration testing on samples of a*
5 *pharmaceutical batch taken after the packaging and sale of the*
6 *remainder of the batch not exempt.*

7 (No. 94-2045 -- Submitted December 12, 1995 -- Decided March 1,
8 1996.)

9 Appeal from the Court of Appeals for Franklin County, Nos. 93APH12-
10 1721 and 93APH12-1722.

11 Roxane Laboratories, Inc. (“Roxane”), appellant, contests the appellee
12 Tax Commissioner’s assessments of sales and use taxes on various items of
13 equipment used for stability testing. The assessments involved the audit
14 periods of January 1, 1983, through December 31, 1985, and January 1, 1986,
15 through December 31, 1988. Both the Board of Tax Appeals (“BTA”) and the
16 court of appeals upheld the assessments.

17 Roxane manufactures generic pharmaceutical products. Roxane does not
18 develop new prescription pharmaceuticals itself. Rather, it waits until an

1 innovative new drug patent has expired and develops a product for sale based
2 upon the expired patent. Because the drugs produced by Roxane have been
3 previously approved by the Federal Food and Drug Administration (“FDA”),
4 Roxane is not required to obtain re-approval of the effectiveness or medicinal
5 value of these drugs. Roxane is, however, required by the FDA to procure pre-
6 approval of each drug it intends to manufacture.

7 In order to obtain this re-approval, Roxane is required by the FDA to test
8 the stability of the drugs it manufactures. The purpose of testing for stability
9 (“stability testing”) is to verify, at set intervals of time, that the drugs have not
10 become ineffective or chemically broken down. The FDA requires that stability
11 testing be done (1) prior to FDA approval in order to develop a protocol for
12 manufacturing the product and to establish future testing procedures, and (2)
13 after the drug is packaged and marketed to assure its continued efficacy by
14 monitoring the product during its expected shelf life. In dispute is the
15 equipment Roxane uses in its stability testing of the packaged drugs.

1 In order to conduct the required on-going stability testing, samples from
2 each pharmaceutical batch are drawn off from the manufacturing process as the
3 product goes into the package and are monitored and tested using the stability
4 testing equipment. If the stability tests are not satisfactory, the drug is deemed
5 adulterated and must be recalled. Stability testing is not performed on the
6 drugs as they are being manufactured, nor does the testing indicate whether the
7 drugs were manufactured properly.

8 Roxane timely appealed the assessments on the stability testing
9 equipment to the BTA. In affirming the assessments, the BTA found that the
10 stability testing was performed either before any manufacturing had begun or
11 after the drug had been packaged and sold, and therefore the stability testing
12 equipment was not entitled to exception under R.C. 5739.01(E)(2) as items
13 used directly in manufacturing. Roxane appealed and the court of appeals
14 affirmed the BTA's decision on this issue.

15 The cause is now before this court pursuant to an allowance of a
16 discretionary appeal.

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2 *Brickler & Eckler and Mark A. Engel; and Brian E. Andreoli, pro hac*
3 *vice*, for appellant.

4 *Betty Montgomery, Attorney General, and Richard C. Farrin, Assistant*
5 *Attorney General*, for appellee.

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7 Cook, J. The issue before this court is whether equipment used to
8 perform FDA testing on samples of a pharmaceutical batch taken after the
9 packaging and sale of the remainder of the batch is exempt from sales and use
10 taxes as an adjunct to manufacturing pursuant to R.C. 5739.01(E)(2). We find
11 that equipment used in stability testing does not qualify as an adjunct to
12 manufacturing under R.C. 5739.01(R), as it is used after manufacturing ends.

13 Roxane challenges the failure to exempt the stability testing machinery
14 from sales and use taxes as an adjunct to manufacturing. Because the use tax
15 adopted the sales tax exemptions, we will address only the sales tax statutes,
16 but the analysis applies equally to the use tax. See R.C. 5741.02(C)(2).

1 Roxane contends that, because the stability testing is required by the
2 FDA, the testing is part of the manufacturing process, and is therefore
3 exempted from sales tax by former R.C. 5739.01(E)(2), which provided:

4 “‘Retail sale’ *** include[s] all sales except those in which the purpose
5 of the consumer is:

6 “ ***

7 “(2) *** to use or consume the thing transferred directly in the
8 production of tangible personal property * * * for sale by manufacturing,
9 processing ***.” (140 Ohio Laws, Part II, 3216.)

10

11 In order for this manufacturing exemption to apply, a taxpayer must meet
12 the definition of “manufacturing” provided in former R.C. 5739.01(R) (now
13 5739.01[S]). During the audit periods in question, the General Assembly
14 focused repeatedly on this definition and changed the language of the statute
15 several times; however, the concept never changed. The legislative changes
16 only clarified the concept by further defining the statutory terms.¹

1 From November 24, 1981 until March 12, 1987, R.C. 5739.01(R)
2 provided:

3 “‘Manufacturing’ or ‘processing’ means the transformation or
4 conversion of material or things into a different state or form from that in
5 which they originally existed and, for the purpose of the exceptions contained
6 in division (E)(2) of this section, includes the adjuncts used during and in, and
7 necessary to carry on and continue, production to complete a product at the
8 same location after such transforming or converting has commenced.” (139
9 Ohio Laws, Part II, 3250.)

10 From March 13, 1987, until October 20, 1987, R.C. 5739.01(R), as
11 amended by Am. H.B. No. 159, 142 Ohio Laws 2109, 2114-2115, provided:

12 “(R)(1) ‘Manufacturing’ or ‘processing’ means the transformation or
13 conversion of material or things into a different state or form from that in
14 which they originally existed. Manufacturing or processing begins at the point
15 where the transformation or conversion commences, or at the point where raw
16 materials are committed to the manufacturing process in a receptacle by being

1 measured, mixed, or blended, whichever occurs first, and it ends when the
2 product is completed.

3 “(2) For the purpose of the exceptions contained in division (E)(2) of
4 this section, things used or consumed directly in manufacturing or processing
5 include the adjuncts used during and in, and necessary to carry on and
6 continue, production to complete a product at the same location after
7 transforming or converting has commenced and before it has ended. Adjuncts
8 include, but are not limited to, machinery and equipment that generates heat or
9 power for production processes and foundations and supports for machinery
10 and equipment used during manufacturing. Machinery and equipment used
11 before manufacturing begins or after manufacturing ends as described in this
12 division are neither used directly in manufacturing nor as adjuncts.

13 “(3) For the purpose of the exceptions contained in division (E)(2) of this
14 section, the fact alone that machinery or equipment, supplies, or services are
15 necessary, essential or crucial to the manufacturing process does not mean they

1 are used directly in the manufacturing process or as an adjunct.” (New
2 language emphasized.)

3 From October 20, 1987, through April 10, 1990, R.C. 5739.01(R)(2), as
4 amended by Am. Sub. S.B. No. 92, 142 Ohio Laws 266, further expanded the
5 definition of “adjuncts” to manufacturing. It provided:

6 “ * * * Adjuncts include, but are not limited to, machinery and
7 equipment that generates heat or power for production processes, foundations
8 and supports for machinery and equipment used during manufacturing, and
9 machinery and equipment used during the manufacturing period to test or
10 check the quality of the thing being manufactured, unless the thing being
11 manufactured is removed from the manufacturing plant or facility for the test or
12 check. Machinery and equipment used before manufacturing begins or after
13 manufacturing ends as described in this division are neither used directly in
14 manufacturing nor as adjuncts.” (New language emphasized.)

15 It is axiomatic that exemptions from taxation are not favored by the law
16 and the intention to grant an exception must be clearly expressed. Meridian

1 Technology Leasing Corp. v. Tracy (1995), 73 Ohio St.3d 387, 389, 653
2 N.E.2d 232, 234, citing Pfeiffer v. Jenkins (1943), 141 Ohio St. 66, 68, 25 O.O.
3 197, 198, 46 N.E.2d 767, 768. Roxane contends that it is entitled to the
4 manufacturing exemption because the stability testing is essential to the
5 salability of the product under the dictates of the FDA. The language of the
6 exemption statutes, however, plainly excludes this equipment.

7 The stability testing equipment is not a part of the transformation or
8 conversion of raw materials into a different state, as “manufacturing” is
9 defined. The testing’s limited purpose is unrelated to the production process.
10 The stability testing is conducted on samples “drawn off” as the product goes
11 into the package. At this point, no further ingredients are added to the product.
12 The transformation is complete before the product is packaged. Thereafter, the
13 stability testing is done at various intervals, while the product is on the market.
14 Such equipment cannot be said to be used “during and in, and necessary to
15 carry on and continue, production to complete a product at the same location
16 after such transforming or converting is commenced” in order to qualify as an

1 adjunct to manufacturing. Nor can the equipment be found to meet the
2 definition that the adjunct be used before the manufacturing process ended.
3 Rather, the equipment is encompassed in the language of the statute which
4 affirmatively excludes as adjuncts, that machinery and equipment used “before
5 manufacturing begins or after manufacturing ends * * * [as] neither used
6 directly in manufacturing nor as adjuncts.”

7 We are unwilling to stretch the language of the statute to adopt Roxane’s
8 view that the product is not complete until it reaches its expiration date.
9 Pursuant to Ohio Adm. Code 5703-9-21(B)(8), a product is “completed” “when
10 all processes that change or alter its state or form or enhance its value are
11 finished, even though the item subsequently will be tested to ensure its quality
12 or be packaged for storage or shipment.” The record discloses that the stability
13 testing in no way changes or alters the product. Rather, the testing is used only
14 to ensure that the product remains safe and effective during its prescribed shelf
15 life.

1 Finally, Roxane argues that because the FDA stability testing is a
2 prerequisite to marketing the product, the testing is essential to the
3 manufacturing process. However, R.C. 5739.01(R)(3) provided that “the fact
4 alone that machinery or equipment, supplies, or services are necessary,
5 essential, or crucial to the manufacturing process does not mean they are used
6 directly in the manufacturing process or as an adjunct.” Therefore, we find that
7 the stability testing equipment used after the product is completely transformed
8 and packaged does not qualify as an adjunct to the manufacturing process
9 which is exempt from sales and use taxes.

10 Other cases from this court cited by the taxpayer are distinguishable. In
11 Jeep Corp. v. Limbach (1989), 47 Ohio St.3d 67, 547 N.E.2d 975, the BTA
12 exempted equipment used to perform tests on the final inspection line before a
13 vehicle was shipped for sale. If the inspection revealed a problem, then further
14 adjustments to the vehicles were made. These tests occurred after most of the
15 final inspection line adjustments had taken place but before the end of the line.
16 The Jeep court stated that it would not overrule the BTA’s finding that all

1 equipment on the final inspection line including the equipment in question was
2 exempted from tax. Jeep Corp., 47 Ohio St.3d at 68, 547 N.E.2d at 977, citing
3 Hawthorn Mellody, Inc. v. Lindley (1981), 65 Ohio St.2d 47, 19 O.O.3d 234,
4 417 N.E.2d 1257, syllabus. We reconcile Jeep with the result here based on the
5 key facts that the vehicles being tested in Jeep were still on the inspection line
6 and the manufacture of the vehicle was not complete at the time the test was
7 performed.

8 In OAMCO v. Lindley (1986), 24 Ohio St.3d 124, 24 OBR 347, 493
9 N.E.2d 1345, clarified (1987), 27 Ohio St.3d 7, 27 OBR 427, 500 N.E.2d 1379,
10 reclarified (1987), 29 Ohio St.3d 1, 29 OBR 122, 503 N.E.2d 1388, a heated
11 conveyor belt was used to transport freshly mixed asphalt into trucks. In
12 allowing the conveyor as an adjunct entitled to tax exception, this court held
13 that the equipment utilized to preserve the required product state is an adjunct
14 to property used or consumed directly in the production of tangible personal
15 property. OAMCO, 27 Ohio St.3d at 8-9, 27 OBR at 428, 500 N.E.2d at 1381.
16 Unlike the conveyor in OAMCO, the stability testing equipment does not act

1 upon the manufactured product, it does not effect any change in state or form,
2 nor does it maintain the form of the product. Further, the stability testing
3 occurs after the drug has been completed, distributed, and sold. Additionally,
4 unlike the stability testing equipment, the conveyor in OAMCO was utilized
5 only at a time prior to delivery of the asphalt to customers.

6 Roxane also argues that because the FDA demands the stability testing,
7 federal law had preempted the state definition of “manufacturing.” Preemption
8 is inapposite to this case because the FDA statutes and the Ohio tax statutes are
9 not in conflict on this subject. The FDA statutes and regulations pertain to
10 manufacturing procedures, while the Ohio tax statutes address Ohio sales and
11 use taxes.

12 Finding that the stability testing equipment does not qualify as an exempt
13 adjunct to the manufacturing process, we affirm the decision of the court of
14 appeals.

15 Judgment affirmed.

1 MOYER, C.J., DOUGLAS, WRIGHT, RESNICK and F.E. SWEENEY, JJ.,

2 concur.

3 PFEIFER, J., dissents.

4 PFEIFER, J., dissenting. The stability testing of appellant's generic drugs

5 is inseparably connected with the manufacture of the drugs. Thus, I would

6 hold that the equipment that appellant uses in the stability testing is an adjunct

7 to manufacturing and is exempt from sales and use taxes.

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¹ Following the audit periods in question, R.C. 5739.01 was amended. We do not address these later amendments because they are not relevant to the time period in question.