
10. Potential Competition: Introduction

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Two potential competition theories

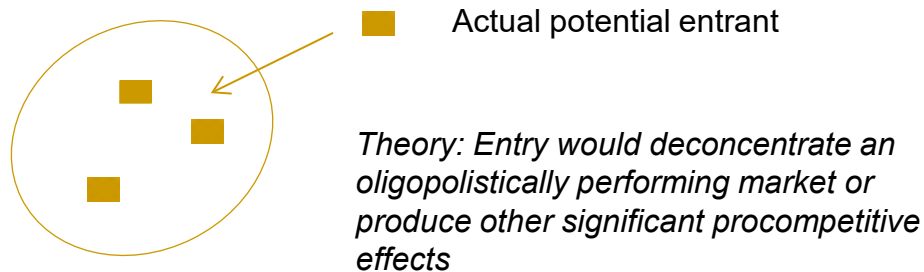
- Elimination of actual potential competition
- Elimination of perceived potential competition

- Related theory: Elimination of nascent competition

Actual potential competition

■ The idea

- A merger may eliminate reasonably probable independent entry that would have reduced concentration or produced other significant procompetitive effects
- The competitive concern is that the merger eliminates future rivalry and leaves the market less competitive than it would likely have been without the merger



Actual potential competition

■ The idea

□ Acceptance by courts

- The Supreme Court has reserved judgment on the elimination of actual potential competition¹
- Some lower courts have recognized the theory; others have assumed its validity without deciding the question
- The FTC and the 2023 DOJ/FTC Merger Guidelines recognize the elimination of actual potential competition as an actionable anticompetitive harm under Section 7
- Both actual and perceived potential competition have proved difficult to establish in contested litigation

□ WDC: The forward-looking comparison

- The contemporary competitive effects inquiry compares likely market conditions with and without the merger
- This comparison supports recognizing the loss of reasonably probable independent entry with significant procompetitive effects
- Compare the structural/concentration perspective of the 1960s/1970s

¹ See *United States v. Marine Bancorporation, Inc.*, 418 U.S. 602, 625, 639 (1974); *United States v. Falstaff Brewing Corp.*, 410 U.S. 526, 537-38 (1973).

Actual potential competition

- Elements of the actual potential competition theory of harm
 1. The relevant market must be operating noncompetitively with room for competitive improvement
 2. The potential entrant must be relatively unique in its ability and incentive to enter the relevant market
 3. The potential entrant must have “available, feasible means” of independent entry
 4. The actual potential entrant must have a reasonable likelihood of entry into the relevant market in the near future
 5. Entry, if it were to occur, must have a reasonable probability of a substantial procompetitive effect

Not all of these elements are specifically identified as such in the case law but are inherent in the precedent and the underlying economic theory

Actual potential competition

■ Noncompetitive market (element 1)

- ❑ The relevant market must be operating noncompetitively, with room for entry to improve its competitive performance substantially
- ❑ High concentration can establish a prima facie showing that the market is a candidate for the doctrine
- ❑ The merging parties may rebut that showing with evidence that the market is genuinely competitive

■ Relative uniqueness of the potential entrant (element 2)

- ❑ Compare the firm's capabilities and incentives with those of other firms positioned to enter the relevant market
- ❑ Eliminating one potential entrant matters more when few other firms have an equal or better ability and incentive to enter effectively
- ❑ Relevant advantages may include distinctive technology, regulatory progress, distribution, access to necessary assets, experience entering comparable markets, and management inclination
- ❑ The inquiry requires evaluating the strength of the remaining entry prospects, including whether other firms could provide a comparable expected competitive benefit

Actual potential competition

■ Available, feasible means (element 3)

- The potential entrant must have an available, feasible route to independent entry; resources and motivation alone are not enough
- Possible routes include *de novo entry* and a *toehold acquisition* capable of supporting significant expansion

■ Likelihood of entry (element 4)

- Entry must be reasonably probable without the merger
- The prediction must reflect the firm's commercial incentives, including alternative uses of its resources¹
- Evidence of likely entry may be objective or subjective; subjective evidence is not required if objective evidence is sufficient²
- Relevant evidence includes ordinary course plans, budgets, capital requests, customer commitments, management testimony, and experience in comparable markets

¹ *Mercantile Tex. Corp. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 638 F.2d 1255, 1269-70 (5th Cir. Unit A 1981).

² *Id.*

Actual potential competition

■ Timing of entry (element 4)

- *BOC*: A supported estimate of entry in the “near future”¹
 - “Near” depends on the industry’s entry barriers and necessary lead time
 - An exact date is unnecessary, but indefinite “eventual entry” is insufficient
- These cases establish no fixed numerical deadline

■ Competitive effect of entry (element 5)

- Separately from predicting whether and when entry would occur, the plaintiff must establish a reasonable probability of a substantial procompetitive effect if entry occurs²
- *Mercantile Texas*: Assess whether the market will remain sufficiently concentrated for entry to improve competition when entry is likely to occur³
 - Longer forecasts require closer examination of market volatility
 - If the market would become competitive before entry, the predicted entry may no longer produce the competitive benefit the doctrine requires

¹ *BOC Int’l Ltd. v. FTC*, 557 F.2d 24, 29 (2d Cir. 1977).

² *Mercantile Tex. Corp. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 638 F.2d 1255, 1271-72 (5th Cir. Unit A 1981).

³ *Id.*

Actual potential competition

■ Guideline 4: Agency enforcement approach¹

□ Concentration

- HHI above 1,000; greater concentration lowers the entry probability that raises concern
- Case law has not adopted a fixed concentration threshold
 - Leading potential competition cases involved substantially higher concentration

□ Probability of entry

- Entry other than through an anticompetitive merger must be reasonably probable
 - Some case law requires some requires entry more likely than not
- Considering organic entry instead of merging generally suggests reasonably probable entry
 - WDC: Case law should accept a permissive inference of reasonably probable entry from a firm considering organic entry, but it would be subject to rebuttal

□ Competitive significance

- Entry must offer a substantial likelihood of deconcentration or other significant procompetitive effects
- Probable entry into a highly concentrated market suggests significant benefits unless substantial direct evidence shows a de minimis effect
 - WDC: Substantial direct evidence showing a de minimis effect seems to require too much for rebuttal

¹ U.S. Dep't of Justice & Fed. Trade Comm'n, Merger Guidelines § 2.4, at 10-11 & n.21 (2023).

Actual potential competition

■ Remedies

- The remedy must preserve or restore the independent competitive opportunity lost through the acquisition
- Divestiture of assets of the actual potential entrant can be problematic—
 - Oftentimes, little to divest from the actual potential entrant (especially if only in the planning stages)
 - May be difficult to ascertain the commitment of the divestiture buyer to enter or the degree of success it is likely to have
- Agencies may accept divestiture of entry-related assets when—
 - There are substantial assets related to entry to be divested, and
 - There is strong reason to believe that the divestiture buyer will have at least as much success in entering as the divestiture seller in the same time period

■ The practice

- Agencies have used the actual potential competition doctrine to obtain consent orders or decrees when—
 - The market is highly concentrated, and
 - The evidence supports reasonably probable independent entry with significant procompetitive effects
- The remedy may instead divest the incumbent product, as proposed for acyclovir in Mylan/Perrigo

Perceived potential competition

■ The idea

- A firm's perceived threat of entry may cause incumbents to moderate their prices ("limit pricing") or compete more vigorously in other ways
- An acquisition that eliminates this threat of entry may remove that present competitive constraint

Theory: Threat of entry causes incumbent firms in an oligopolistically structured market to perform more competitively premerger



Perceived potential entrant
(waiting "in the wings")

■ Theory recognized by the Supreme Court

- The Supreme Court has recognized the elimination of perceived potential competition as a valid theory of anticompetitive harm
- Guideline 4 of the 2023 Merger Guidelines expressly addresses this theory
 - Direct evidence of incumbents' reactions is not required
 - A likely influence on existing competition may be established by circumstantial evidence

Perceived potential competition

■ Elements of the perceived potential competition theory of harm

1. *Non-competitiveness*

- In order for the elimination of perceived potential competition to have any anticompetitive effect, the market must be one in which the perceived threat of entry can constrain incumbent firms' market power

2. *Uniqueness*

- As under the actual potential competition doctrine, the perceived potential entrant must be perceived as somewhat unique in its incentives and ability to enter the relevant market

3. *Perception as a likely potential entrant*

- Incumbent firms must perceive the firm as a likely potential entrant
- Objective evidence of the potential entrant's capabilities and incentives to enter the relevant market is probative of the perception of the firm as a likely potential entrant¹

¹ United States v. Falstaff Brewing Corp., 410 U.S. 526, 533-34 & 534 n.13 (1973).

Perceived potential competition

■ Elements of the perceived potential competition theory of harm

4. *Incumbent reaction to the threat of entry*

- Incumbent firms must be shown to be responding to the perceived threat of entry by maintaining lower prices, higher product quality, or other more favorable competitive terms than they otherwise would²
- This competitive influence may be established by direct or circumstantial evidence; an observed price cut or an admission of entry-detering intent is not required²

5. *Anticompetitive effect*

- The acquisition must remove or weaken that competitive constraint, creating a reasonable probability of a substantial lessening of competition in the market²

■ Notes

- Again, not all of these elements are specifically identified as such in the case law but are inherent in the precedent and the underlying economic theory

² United States v. Marine Bancorporation, Inc., 418 U.S. 602, 624-25, 639-40 (1974); *Falstaff*, 410 U.S. at 534 n.13; United States v. Siemens Corp., 621 F.2d 499, 505, 509 (2d Cir. 1980).

Perceived potential competition

■ Proof

- The plaintiff need not prove that the potential entrant would actually have entered independently

■ Remedies

- Relief may include enjoining the transaction or an effective divestiture that preserves or restores the lost independent competitive constraint

Potential expander cases

■ *A slight variation: “Potential expander” cases*

- A large firm enters the target market to “test the waters” and obtains a small market share
 - Typically, by shipping into the target market from another market
- But finding de novo entry unattractive, the firm acquires a substantial incumbent firm in the target market

At one time, the agencies attacked these types of acquisitions as eliminating actual potential competition by the large firm¹

- Technically, the agencies may try these cases as horizontal acquisitions since the acquirer did have a “toehold” position in the relevant market. The agencies then argue that given the acquirer’s interest in expanding into the market, the acquirer’s small current market share significantly understates its future competitive significance in the absence of the acquisition
- Acquirers defend by showing that de novo entry is not in their profit-maximizing interest and that they are neither an actual potential entrant nor a “potential expander” in the absence of the acquisition
- Guideline 4 of the 2023 Merger Guidelines expressly addresses the elimination of future competition from entry or expansion

¹ See, e.g., Complaint, *In re* BASF Wyandotte Corp., 100 F.T.C. 261, 263 (Apr. 5, 1979) (alleging that BASF, with a 2% share of sales of organic pigments in the United States, was a potential expander, and therefore that its pending acquisition of Chemetron’s Pigment Division, with a share of 9.2% in the U.S. sale of organic pigments, violated Section 7), *dismissed, id.* at 264 (no appeal to the Commission taken).

A final note

*Under either theory, the potential entrant
may be either the target or the acquirer*

Potential competition and entry

- The plaintiff's potential competition case
 - The merger eliminates a merging firm's prospective rivalry or the present pressure created by its perceived entry
- Entry as rebuttal
 - The defendants contend that entry by other firms will be timely, likely, and sufficient to replace competition lost through the merger
- Different competitive losses¹
 - Entry may be competitively significant without being sufficient to replace the competition lost between established rivals
 - Guideline 4 distinguishes the likelihood needed to establish harm from the likelihood needed to rebut a demonstrated risk of harm

¹ U.S. Dep't of Justice & Fed. Trade Comm'n, Merger Guidelines § 2.4.C, at 12-13 (2023).

Mylan/Perrigo



Mylan/Perrigo (2015)

■ The deal

- ❑ On September 14, 2015, Mylan launched a hostile tender offer to acquire all outstanding ordinary shares of Perrigo for approximately \$27 billion (stock and cash)
- ❑ The offer lapsed on November 13, 2015, because Mylan did not obtain the required acceptance threshold

■ Mylan

- ❑ Global generic and specialty pharmaceuticals company
- ❑ 2015 revenues: \$9.43 billion

■ Perrigo

- ❑ International manufacturer of private label over-the-counter pharmaceuticals
- ❑ Fiscal 2013 net sales: \$3.54 billion

■ Backstory

- ❑ Mylan may have wanted to acquire Perrigo to fend off a \$40 billion hostile offer from Teva Pharmaceuticals

Mylan/Perrigo (2015)

■ Actual overlaps (4)

1. Bromocriptine mesylate tablets
 - Treat conditions including type 2 diabetes and Parkinson's disease
2. Clindamycin phosphate/benzoyl peroxide gels
 - Treat acne (Perrigo's product FDA-approved but not yet launched)
3. Liothyronine sodium tablets
 - Treat hypothyroidism
 - Treat or prevent enlarged thyroid glands
4. Polyethylene glycol 3350 OTC oral solution packets
 - Laxative used to treat occasional constipation

Query: Why did the FTC expect entry into these markets in the near future?

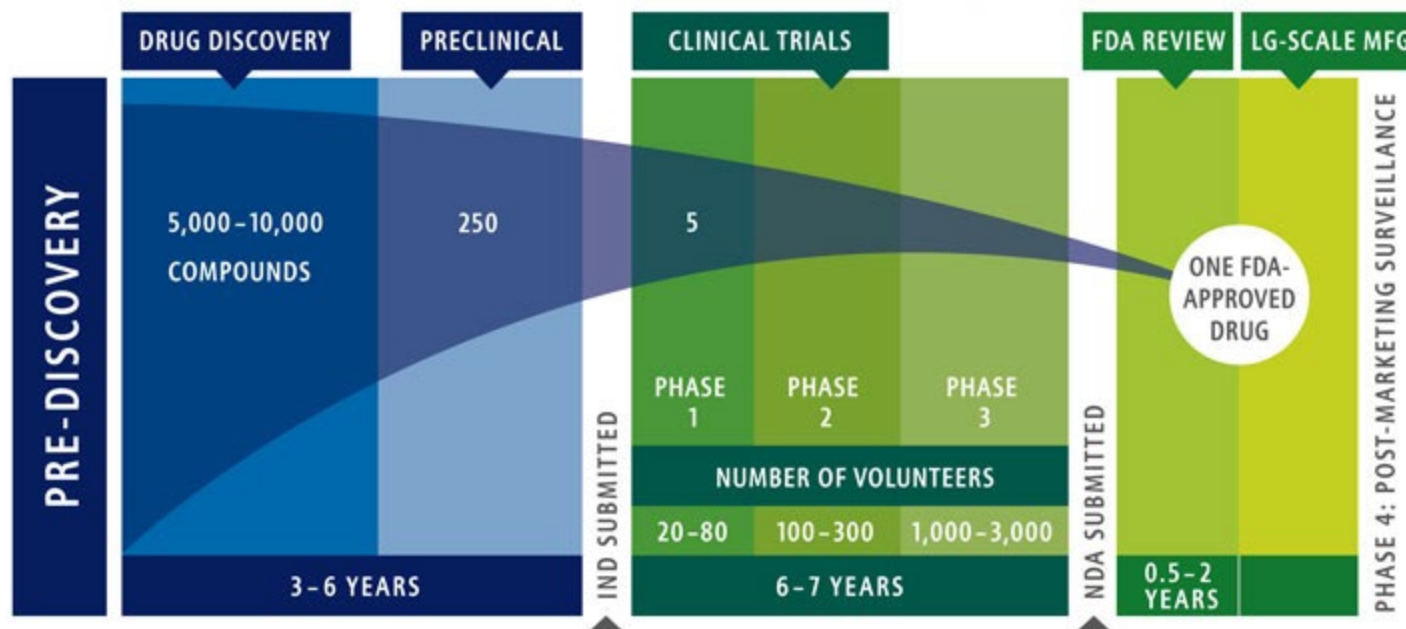
■ Potential future overlaps—Actual potential competition (3)

1. Acyclovir ointment (Perrigo entering)
 - Slows the growth and spread of the herpes virus in the body
2. Hydromorphone hydrochloride extended-release tablets (Mylan entering)
 - Treat moderate to severe pain in narcotic-tolerant patients
3. Scopolamine extended-release transdermal patches (Mylan entering)
 - Prevent nausea and vomiting associated with motion sickness and recovery from anesthesia and surgery

Mylan/Perrigo (2015)

- New drug approval process

Drug Discovery and Development: A LONG, RISKY ROAD



Source: Pharmaceutical Research and Manufacturers of America

Mylan/Perrigo (2015)

■ Generic drug approval process

□ Definition

- A generic drug is comparable to an existing brand name drug in dosage form, strength, route of administration, quality, performance characteristics, and intended use
 - Essentially a knockoff of a brand-name drug

□ Regulatory approval under the Hatch-Waxman Act¹

- **ANDA:** To encourage the introduction of generic drug equivalents as soon as a name-brand drug's patent expires (or is shown to be invalid), Congress and the FDA have created an abbreviated new drug application (ANDA) process
 - The application is "abbreviated" because it generally does not require repeating the innovator's full preclinical and clinical safety-and-effectiveness studies
 - Instead, the generic applicant must scientifically demonstrate that its product is *bioequivalent* to the name-brand drug
- **FDA approval:** Once the FDA approves the application, the applicant may manufacture and market the generic drug product, subject to applicable patent and exclusivity barriers
- **Exclusivity:** The first qualifying applicant(s) to file a substantially complete ANDA with a paragraph IV patent challenge may receive 180 days of exclusivity against later ANDA applicants
 - Under the post-2003 rules, the period begins with first commercial marketing by a first applicant, subject to forfeiture

¹ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585; 21 U.S.C. § 355(j)(5)(B)(iv), (D).

Mylan/Perrigo (2015)

■ Remedies and stages of development

- Mylan/Perrigo (2015)—Marketed and pipeline products
 - The proposed consent required Mylan to divest its U.S. rights and assets in seven marketed and pipeline products to Alvogen, Inc., an experienced generic pharmaceutical company
 - For acyclovir, the proposed remedy divested Mylan's marketed product while preserving Perrigo's prospective entry
- Hikma/Custopharm (2022)—Custopharm approved; Hikma in development
 - Custopharm's triamcinolone acetonide (TCA) product had FDA approval; Hikma's competing product remained in development
 - Water Street (a PE firm that controlled Custopharm) retained and transferred Custopharm's TCA assets to Long Grove Pharmaceuticals, LLC, another portfolio company outside the acquisition
 - Long Grove ordered to operate and maintain Custopharm's TCA assets for four years
 - FTC may appoint a monitor to report on the companies' compliance with the order's requirements
- Allergan/Inamed (2006)—Phase III
 - Inamed required to return Reloxin development and distribution rights, including ongoing trials, to Ipsen; Reloxin was in Phase III

Mylan/Perrigo (2015)

■ Remedies and stages of development

- Sanofi/Aventis (2004)—Phase II/III studies of additional indications
 - Camptosar was already marketed; the remedy transferred Aventis's clinical studies, including a Phase II/III gastric cancer study, and related assets to Pfizer
- Cephalon, Inc./CIMA Labs (2004)—CIMA product in Phase III
 - CIMA's OraVescent fentanyl was in Phase III and would compete with Cephalon's marketed Actiq
 - Cephalon ordered to license generic Actiq to Barr
- Glaxo Wellcome/SmithKline Beecham (2001)—Phase III trials planned
 - Glaxo ordered to return DISC-HSV prophylactic vaccine development rights to Cantab; Glaxo and Cantab had planned Phase III trials

Medtronic/Covidien (2014)



Medtronic
When Life Depends on Medical Technology



Medtronic/Covidien (2014)

■ The deal

- Medtronic to acquire Covidien for \$42.9 billion
 - Announced June 15, 2014
 - 29% premium to Covidien's closing stock price the day before announcement
 - Expect \$850 million in annual pretax cost synergies
 - Medtronic commits \$10 billion in additional U.S. technology investments over 10 years

■ Medtronic

- Global medical technology and services company

■ Covidien

- Global healthcare products company

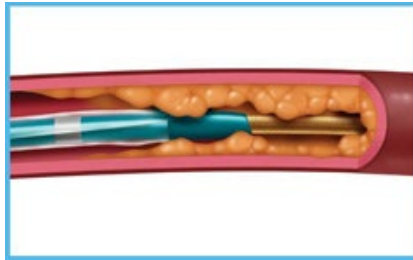
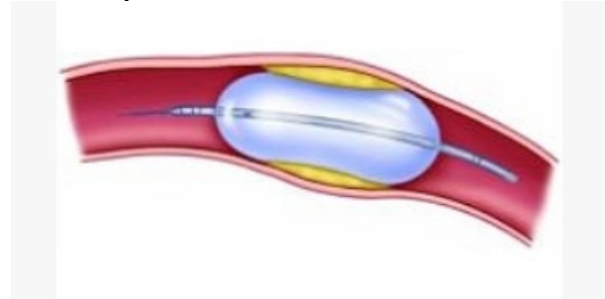
■ Combined company

- Combined revenue: \$27 billion
- 87,000 employees in more than 150 countries

Medtronic/Covidien (2014)

■ The FTC concern

- In 2014, C.R. Bard was the only U.S. supplier of drug-coated balloon catheters indicated for the femoropopliteal (fem-pop) artery
 - Used to treat peripheral artery disease in the artery above the knee



- Medtronic and Covidien were developing competing fem-pop drug-coated balloon catheters
 - Only prospective entrants that had reached clinical trials in the FDA approval process
- ■ Merger of two actual potential entrants into a monopoly market
- Expected second and third U.S. suppliers; the merger could prolong a duopoly

■ Consent order

- Medtronic to sell Covidien's rights and assets related to Covidien's drug-coated balloon catheters business to Spectranetics
 - Spectranetics was a leader in peripheral vascular solutions with a portfolio of products highly complementary to Covidien's drug-coated balloon catheter

Steris/SynergyHealth (2015)



Steris/SynergyHealth (2015)

■ The deal

- Steris to acquire Synergy for \$1.9 billion
 - Announced October 13, 2014

■ Steris

- Second largest sterilization company in the world
- Largest provider of gamma radiation sterilization services in the United States with 12 facilities
- Also has 10 ethylene oxide ("EO") gas sterilization facilities

■ SynergyHealth

- Third largest sterilization company in the world (2014 revenues: \$604 million)
- Operates more than 36 contract sterilization facilities outside of the United States
 - Primarily gamma radiation facilities
 - Däniken, Switzerland—a gamma ray/x-ray facility
 - Only facility in the world providing x-ray sterilization services on a commercial scale
- BUT currently offers only e-beam and EO sterilization services in the United States

Steris/SynergyHealth (2015)

■ Three primary methods of contract sterilization used in the U.S.

1. Gamma sterilization

- Sterilizes by exposing products to photons from radioactive isotope Cobalt-60
- Good penetration even at high densities
- Compatible with most materials
- Only viable option for dense products and products packaged in larger quantities
- Turn-around time: Hours

2. E-beam sterilization

- Sterilizes by exposing products to ionizing energy (electrons) from electron beam
- Does not penetrate as deeply as gamma radiation
- Can be effective for low-density products sterilized in low volumes
- Represents only 15% of all contract radiation sterilization services in the United States
- Turn-around time: Minutes

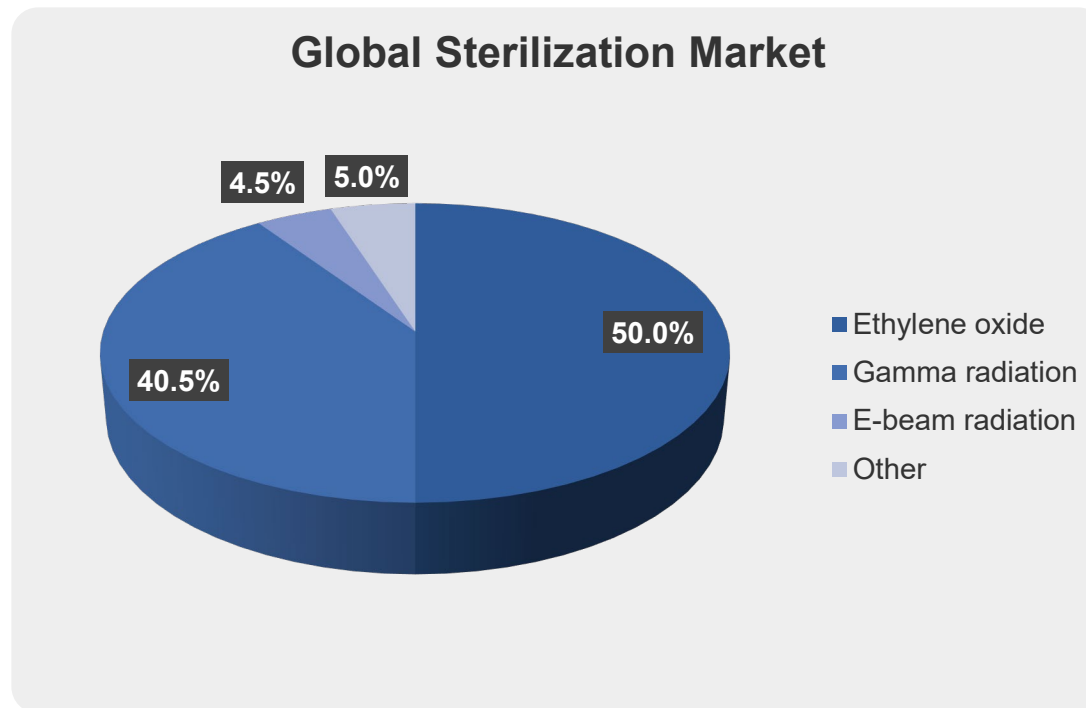
3. Ethylene oxide gas (EO)

- Sterilizes by exposing products to a sterilant gas to kill unwanted organisms
- Requires gas permeable packaging and product design
- Turn-around time: 9-10 days

Steris/SynergyHealth (2015)

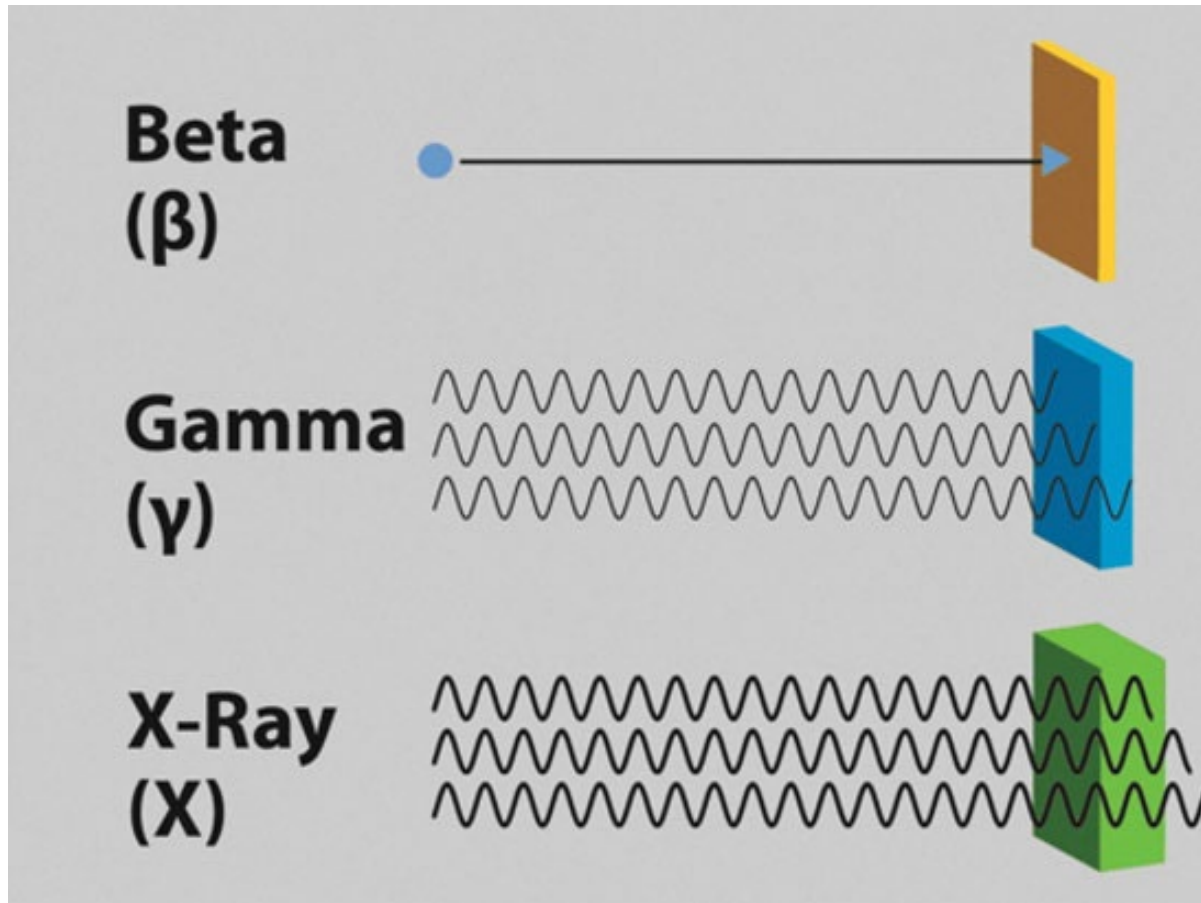
■ Customer choice calculus

- Customers choose sterilization methods based on their products' physical characteristics and packaging



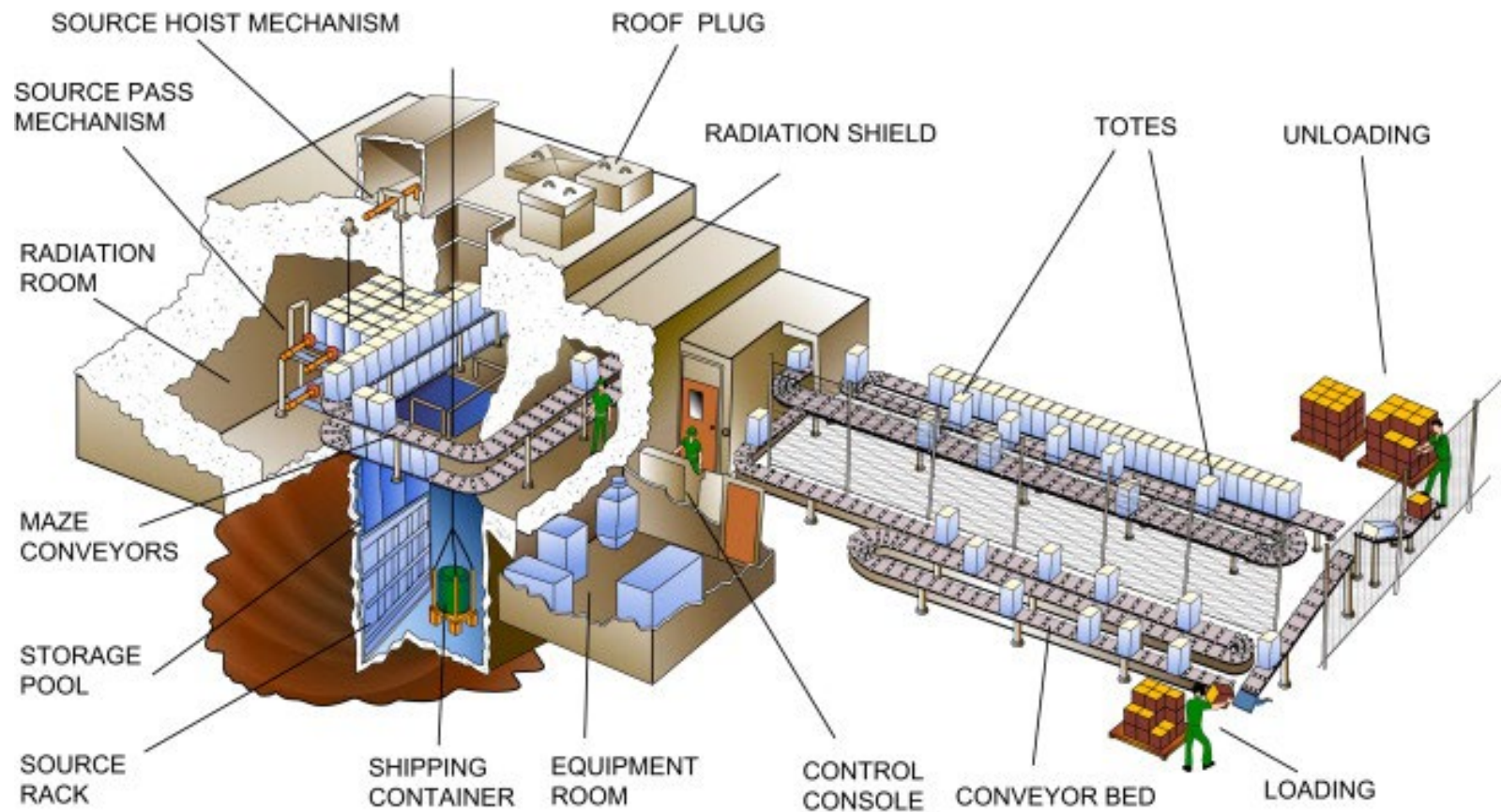
Source: GIPA/ia (2017), p. 8. Global background; these are not shares in the U.S. market litigated in Steris.

Steris/SynergyHealth



Steris/SynergyHealth (2015)

Gamma Irradiation Services Plant



Steris/SynergyHealth (2015)

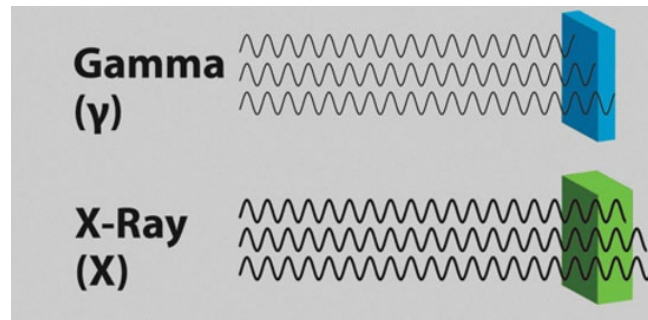
Gamma Irradiation Services Plant



Steris/SynergyHealth (2015)

■ The FTC concern

- There are only two gamma radiation sterilization providers in the United States:
 - Sterigenics (14 facilities)
 - Steris (12 facilities)
- *Allegation:*
 - Absent the acquisition, Synergy would have entered the U.S. with a new x-ray sterilization facility to compete directly with Sterigenics' and Steris' gamma sterilization services
 - According to the FTC, x-ray sterilization is a competitive alternative to gamma sterilization because it has comparable, "and possibly superior," depth of penetration and turnaround times



- *Claim:* Steris' acquisition of Synergy would have insulated Steris' gamma sterilization services from Synergy's prospective entry with x-ray sterilization

Steris/SynergyHealth (2015)

- The FTC's complaint
 - Relevant product markets
 - Contract radiation sterilization services
 - Contract gamma and x-ray sterilization services to targeted customers that cannot economically or functionally switch to e-beam sterilization
 - Relevant geographic markets—defined by facility location
 - “[W]ithin approximately [redacted] miles of each of the locations where Synergy planned to build an x-ray sterilization plant”
 - Likely anticompetitive harm: Elimination of a unique actual potential entrant

Steris/SynergyHealth (2015)

■ District court

- Following a three-day evidentiary hearing, the court denied the FTC's request for a preliminary injunction
- The court assumed, *arguendo*, that the elimination of actual potential competition is a cognizable theory

- The court's
formulation
1. Highly concentrated market
 2. Alleged potential entrant “probably” would have entered the market “within a reasonable period of time” absent the merger
 3. Such entry would have had procompetitive effects
 4. Few if any other firms could enter the market effectively

Prior to the hearing, the Court directed the parties to focus their attention on the second element in the court's formulation (likelihood of entry)

Steris/SynergyHealth (2015)

■ FTC argument on likelihood of entry

- *Core claim:* Absent the acquisition, Synergy would probably have entered the U.S. market by constructing one or more X-ray facilities within a reasonable period of time
 - *Board endorsement:* Synergy's PLC Board endorsed a U.S. X-ray expansion strategy in September 2014
 - *Timing:* By fall 2014, Synergy was allegedly poised to proceed with construction; its September plan contemplated the first two facilities operating by fiscal year 2016
 - *Pretextual abandonment:* Synergy abandoned the project because of the pending acquisition by Steris
 - Synergy terminated the project on February 24, 2015, during the FTC's investigation; the FTC argued that this was done to salvage the merger rather than because de novo entry was impracticable
 - *Credibility:* Documents created and testimony given after the merger announcement should be viewed "with a high degree of suspicion," as self-serving and inconsistent with premerger intent
 - *Revival inference:* If the merger was enjoined, Synergy would likely revive plans and build one or more U.S. X-ray facilities in the near future

Steris/SynergyHealth (2015)

■ The Court's findings

- ❑ After the hearing, the Court found that the FTC failed to show that Synergy probably would have entered the U.S. but for the transaction
- ❑ The FTC failed to show, by a preponderance of the evidence, that it was likely to succeed on the merits in the administrative trial

■ WDC: The three-step framework

- ❑ The FTC probably made out a prima facie case and so satisfied Step 1
- ❑ But the merging parties introduced evidence in Step 2 that put the element in issue
- ❑ At Step 3, the evidence as a whole did not establish likely entry absent the merger

Steris/SynergyHealth (2015)

■ The Court's view of the evidence

□ Governance/approvals

- September 2014 *strategy* was endorsed, but *no business plan* was approved
- Moreover, the business model presented to the Senior Executive Board (SEB) in September 2014 failed Synergy's internal hurdle metrics
 - IRR target: 15%; projected IRR was 6.51%, falling to 3% after correction of double-counted Lima revenues
 - Cash payback target: No more than five years; projected payback was 7.7 years
- Synergy's Senior Executive Board (SEB) lacked authority to approve capital expenditure greater than £10 million
- Synergy PLC's Board of Directors never saw or approved a business plan to actually enter the United States
 - First-phase greenfield X-ray entry in the U.S. required more than \$40 million, about \$20.2 million per plant
- Only specific spend approvals were two deposits to Ion Beam Applications S.A. (IBA) for exclusive options on the purchase of X-ray accelerator machines for two potential U.S. facilities

□ Work continued after announcement

- The October 2014 merger announcement did not halt the U.S. X-ray effort
- Synergy kept courting customers, negotiating site incentives, refining the model, and working with IBA
- The Court found this evidence inconsistent with a pretextual abandonment

Steris/SynergyHealth (2015)

■ The Court's view of the evidence

□ Lack of customer commitments

- *Corporate policy*: Secure take-or-pay customer contracts before any greenfield sterilization build (a prerequisite to clear internal finance/SEB review for large capex).
- Outreach to 185 firms yielded 6 non-binding LOIs and no take-or-pay contracts
- The most significant reason for discontinuation of the project was lack of customer commitments

□ Why customers balked

■ Low cost impact

- Sterilization accounts for only 3% of total device cost—so even large % price savings had little total-cost impact
- Even a 30% sterilization savings would yield only a 1% reduction in total device cost

■ High switching and validation costs

- Converting a product from gamma to X-ray sterilization required extensive testing, regulatory approvals (FDA and foreign authorities), and site qualification
- Cost of \$250,000–\$500,000 per product
- Approvals likely to take several years

■ Operational risk

- Because no other U.S. x-ray facilities yet existed, manufacturers would have no alternative capacity if Synergy's new x-ray plant went offline
- By contrast, both gamma-ray sterilization suppliers had multiple facilities across the country

Steris/SynergyHealth (2015)

- The Court's view of the evidence
 - Synergy's experience at Däniken (Switzerland)
 - Low utilization
 - Däniken X-ray facility was only running at about 25% capacity after several years of operation
 - Suggested limited medical-device demand despite several years of operation
 - Customer behavior
 - Attempts to push gamma-to-X-ray switches at Däniken met resistance from device makers concerned about conversion costs, validation time, and backup capacity
 - Capital costs/equipment
 - The U.S. plan required a dual X-ray/e-beam machine with 400 kW X-ray capacity that had not been built or tested
 - Estimated construction costs rose by \$2.5 million; the required machine would cost more than originally estimated
 - Court's conclusion
 - Even enthusiastic customers remained “totally non-committal” on volume, concluding that potential cost savings did not justify conversion risk or delay
 - The Synergy PLC Board likely would never approve construction of a U.S. plant under these conditions

FTC's petition for a preliminary injunction denied

Steris/SynergyHealth (2015)

■ Outcome

- ❑ The FTC dismissed its administrative complaint
- ❑ STERIS closed the acquisition of SynergyHealth on November 2, 2015

■ The lessons

- ❑ A finding of likely independent entry requires a commercially supported prediction, evaluated against contemporaneous plans and market conditions
- ❑ Corporate approvals, customer commitments, and financial projections are evidence of likely entry; no particular approval stage is invariably required¹

■ Next class: Unit 11

- ❑ *Meta/Within*: Apply the actual and perceived potential competition doctrines and examine why the FTC's proof failed
- ❑ *Edwards/Jena Valve*: Examine how firms can already compete in product development and clinical trials before commercial sales begin
- ❑ *Nascent competitive threats*: Compare Section 7 and Section 2 monopoly maintenance as grounds for challenging acquisitions of emerging threats to dominant firms when their future competitive significance is uncertain

¹ FTC v. Meta Platforms Inc., 654 F. Supp. 3d 892, 932, 934-35 (N.D. Cal. 2023).