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Kira Le*

For patients with breast cancer whose cancer has metastasized, or spread beyond its original site to a nonadjacent location, treatment options are limited.¹ The vast majority of individuals with metastatic breast cancer will die from the disease, and anticancer drugs are among the only life-prolonging treatments available.² Because metastatic breast cancer is incurable, treatment options are used consecutively or simultaneously, meaning anticancer drugs are rarely in competition with one another. In effect, this “creates a virtual monopoly because the use of one drug does not automatically mean that the others are no longer needed.”³ Even when new drugs enter the market, they tend to not be in competition with older ones, because they are viewed as substandard treatment.⁴ Accordingly, the cost of treating metastatic breast cancer, and of these drugs, specifically, is exorbitantly high, leaving terminal patients reeling from the broad effects of financial toxicity. The serious nature of terminal cancer, taken in conjunction with the lucrative financial incentives offered to oncologists in exchange for their administration of these drugs, results in patients paying the high price of treatment “even for marginal

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* J.D. Candidate, 2024, University of Minnesota Law School; B.A., The George Washington University, 2020. I would like to thank Professor Susan M. Wolf for her advice and guidance throughout the writing process, Dan O'Dea and the MJLST editors and staff for their edits and feedback, and my beloved husband Noah Burroughs for his unending support and encouragement. All opinions and mistakes are my own.

² Id. at 141.
³ Mustaqeem Siddiqui & S. Vincent Rajkumar, The High Cost of Cancer Drugs and What We Can Do About It, 87 MAYO CLINIC PROC. 935, 935 (2012).
⁴ Id.
improvements in outcome."5 As a result, cancer drugs make up an increasingly large portion of pharmaceutical companies’ revenue, increasing by seventy percent between 2010 and 2019 among ten large pharmaceutical companies. In contrast, revenues from non-cancer medicines decreased by eighteen percent.6

This Note will demonstrate that some or all of the pharmaceutical companies that manufacture these drugs, such as Bristol-Myers Squibb, Eli Lilly and Company, Genentech, Pfizer, and Teva Pharmaceuticals are likely violating federal antitrust laws by monopolizing the market of treatments of this advanced stage of breast cancer. It will also explore how these companies have willfully maintained market monopolization by ensuring costs for patients remain high and neglecting to develop new drugs that would offer meaningful improvements in sustaining life for patients. It will argue that anticompetitive settlement agreements and certain drug patents violate the essential facilities doctrine, that the pharmaceutical companies who manufacture and own these metastatic breast cancer drugs engage in pricing practices that violate federal antitrust law, and will call on the Federal Trade Commission to prevent the unfair methods of competition that these companies use. Specifically, the FTC should issue an advisory opinion addressing the legality under U.S. antitrust laws of the various practices of pharmaceutical companies engaged in the production of advanced cancer drugs. It should investigate the firms holding the most market power in the metastatic breast cancer pharmaceutical industry, prepare reports and conduct hearings based on its findings, seek injunctive relief against the companies engaging in anticompetitive conduct, and make rules to ensure antitrust laws are followed going forward.

I. BACKGROUND

A. MONOPOLIZATION

Section 2 of the Sherman Act prohibits “monopolization, attempted monopolization, and conspiracies to monopolize.

5. Id.

Monopolization . . . appl[ies] primarily, but not always, to the unilateral conduct of single companies that obtain or maintain monopoly power, or threaten to do so, by conduct that excludes competitors without otherwise benefitting consumers.\(^7\) Even if a company has obtained substantial market power legitimately, engaging in exclusionary or predatory conduct to prevent competition against it is also illegal under federal antitrust law.\(^8\) Further, conduct that may be perfectly legitimate in a competitive market may nonetheless be unlawful for companies with substantial market power.\(^9\) “In general, a plaintiff can prove that [a] defendant has market power by either direct evidence or circumstantial evidence. Direct evidence of market power includes evidence of actual restricted output, persistent supracompetitive prices, persistent price discrimination, persistent supracompetitive returns, and lower quality.”\(^10\) In order to prove market power by circumstantial evidence, a plaintiff must show (a) that the defendant has a large market share and, (b) that both entry barriers and expansion barriers for other companies are high, “making an increase of output unlikely.”\(^11\) Entry barriers include any costs incurred to enter the market that incumbent companies did not have to incur, such as “licensing, patents, or certificate-of-need requirements; capital costs; sunk costs; product differentiation; access to inputs; reputation; and economies of scale.”\(^12\) Although a dominant company creating these barriers can raise antitrust concerns, it is irrelevant to the assessment of the effect of entry barriers whether such a company with market power caused them.\(^13\)

B. BASELESS PATENT INFRINGEMENT LAWSUITS AGAINST GENERIC COMPETITORS

In her 2020 article in *Pharmacy in History* titled, “The Yew Tree and the Crab: A Case Study of Big Pharma, Small Pharma, and an Anti-Cancer Drug,” Professor Jacalyn Duffin tells the story of how pharmaceutical company Bristol-Myers Squibb

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8. *Id.* at §1:4.
9. *Id.*
10. *Id.*
11. *Id.*
12. *Id.*
(BMS) trademarked the research term and accepted chemical name “taxol” for its metastatic breast cancer drug, an “extraordinary action [that]... was roundly criticized in the major scientific journals, including Nature, which declared that BMS ‘should be ashamed of itself’ and should ‘return the name to the research community.’”14 After receiving a patent, BMS went on attempt to eradicate all competitors, suing Biolyse for using the name taxol to describe its product, even though the word had been created by publicly-funded scientists, the company’s clinical trial began before the term was trademarked, and the term served as the chemical name for the prior twenty years.15 “Eventually, the attorneys general of thirty... states sued BMS, charging that its illegal, antitrust strategies characterized by ‘frivolous’ and ‘fraudulent’ lawsuits were blocking generic competition...”16 In 2003, the Federal Trade Commission filed a complaint, alleging that BMS “engaged in a pattern of anticompetitive activity over the past decade in order to delay generic competition and maintain its monopoly over... highly profitable branded drugs.”17 Similarly, in 2002, suits brought in state courts claimed that the patent holder on breast cancer drug tamoxifen violated state antitrust laws by improperly restricting distribution of generic versions of the drug.18

C. ANTICOMPETITIVE SETTLEMENT AGREEMENTS

In the aforementioned case, In re Tamoxifen Citrate Antitrust Litigation, Zeneca and Barr Pharmaceuticals entered into a settlement agreement under which Barr agreed to not market a generic version of the drug until Zeneca’s patent expired in exchange for twenty-one million dollars and a license to sell tamoxifen under a generic label.19 The agreement spawned thirty lawsuits throughout the U.S., alleging that the

15. Id.
16. Id. at 12–13.
17. Toby G. Singer (Moderator) et al., Views from Federal and State Antitrust Enforcers, 20100524 AHLA SEMINAR PAPERS, May 2010 at 1, 10 (citing In the Matter of Bristol-Myers Squibb Company, 135 F.T.C. 444 (2003)).
19. Id. at 328.
agreement avoided price competition, maintained artificially inflated market prices for the drug and its generic, and excluded competition from other generic manufacturers. The district court dismissed the complaint, which was then affirmed by the Second Circuit. However, the Sixth Circuit has adopted a rule of per se illegality for such settlement agreements, and the Eleventh Circuit has endorsed inquiries into the validity of the underlying patents in such circumstances. Indeed, in 2013, the U.S. Supreme Court held in *F.T.C. v. Actavis, Inc.*:

[A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments. In our view, these considerations, taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements.

### D. Predatory Conduct

The concept of predatory conduct “generally refers to conduct by a defendant with substantial market power that prevents its competitors from constraining that power and that furthers none of the values competition is meant to promote: lower prices, enhanced efficiency, higher quality, greater product variety, wider access, better service, and greater innovation.” By using broad, ambiguous language in prohibiting “unfair methods of competition” in the Federal Trade Commission Act, Congress afforded the FTC broad discretion in determining whether conduct constitutes such. Section 5 of the statute further prohibits conduct not constituting technical

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20. *Id.* at 329.


23. MILES, supra note 7, at § 6:4.

24. *Id.* at § 7:13.
violations of the Sherman and Clayton Act but are violations of their “spirit.”

E. SELLING TO DIFFERENT CUSTOMERS AT DIFFERENT PRICES

Section 2(a) of the Clayton Act, as amended by the Robinson-Patman Act, the statute’s most important provision, “prohibits sellers from selling commodities to different customers at different prices in circumstances where the price differential might result in an anticompetitive effect.” In the cancer drug industry, confidential discounts or rebates are used to allow the list prices for drugs to remain high “in preparation for future negotiations with potential buyers.” Pharmaceutical companies also use these practices to apply price discrimination – pricing according to buyers’ willingness to pay. Confidential agreements also prevent competitors (and everyone else) from ascertaining pricing strategy and methodology. Because oncologists derive more than fifty percent of their revenues from administering cancer drugs, their drug choices are responsive to the profit margins of the pharmaceutical companies producing them. Oncologists purchase drugs used to treat metastatic breast cancer “from manufacturers or distributors, administer them in their offices, and bill patients’ insurers, with explicit financial incentives linked to drug choice for physicians” through the “buy and bill” reimbursement system.

F. MERGERS AND ACQUISITIONS

In 2009, the Federal Trade Commission filed a complaint alleging that Teva Pharmaceutical Industries’ acquisition of Barr Pharmaceuticals would decrease competition in drug markets such as the metastatic breast cancer drug tamoxifen.

25. Id.
26. Id. at § 7:2.
28. Id.
29. Id.
30. Howard et al., supra note 1, at 144.
32. Singer (Moderator) et al., supra note 17, at 45.
The two pharmaceutical companies combined owned seventy-three percent of the generic tamoxifen market. Horizontal mergers, such as Teva’s acquisition of Barr, terminate competition and raise antitrust concerns when the result increases a company’s market power in a highly concentrated market. Most U.S. courts permit either an inference or rebuttable presumption of monopoly power when a company owns a market share of at least sixty-five to seventy percent.

II. ANALYSIS

A. MONOPOLIZATION

In their comparative analysis of prices and within-class competition of cancer drugs in the United States and Europe, Kerstin N. Vokinger and her colleagues found that since at least January of 2009, the cost of solid cancer drugs, which includes breast cancer, has increased “regardless of whether or not competitors entered the market.” Cancer drug prices have steadily increased in the United States, unconstrained by the introduction of new drugs into the market. Rather, prices increased during time frames in which new drugs were brought to market. Furthermore, “[p]rice changes between competitor drugs were not more strongly correlated than between non-competitor drugs.” Vokinger and colleagues noted that other studies assessing cancer drug prices in the United States “have similarly suggested little competitive pressure in the anticancer drug market, with steady price increases after launch . . .” As discussed above, Section 2 of the Sherman Act prohibits monopolization, which applies to companies that obtain or maintain monopoly power. Substantial market power is necessarily required for a company to hold monopoly power in

33. Id. at 46.
34. MILES, supra note 7, at § 4:8.
35. Id. at § 5:3.
37. Id. at 515.
38. Id. at 517.
39. Id.
40. Id.
41. MILES, supra note 7, at § 6:1.
restraint of competition. The persistent supracompetitive prices—prices higher than what can be sustained in a truly competitive market—is an example of direct evidence plaintiffs can use to prove the existence of a defendant's substantial market power in the metastatic breast cancer drug market. This showing is required for a plaintiff to demonstrate an antitrust violation.\textsuperscript{42}

In 2017, the World Health Organization assessed the market share of cancer drugs by calculating the Herfindahl-Hirschman Index (HHI), a common measure of the market concentration of an industry in order to determine its competitiveness.\textsuperscript{43} The resulting analysis found a highly concentrated market for breast cancer, demonstrating a lack of competition in the market.\textsuperscript{44} As previously noted, the lack of competition in a market where monopoly power exists does not, on its own, constitute an antitrust violation. However, the lack of competition in the breast cancer drug market is caused by companies with substantial market power engaging in both exclusionary and predatory conduct to prevent competition, which does violate antitrust law. Furthermore, although companies may obtain substantial market power legitimately and without raising antitrust concerns, breast cancer drug pharmaceutical companies create the entry barriers that prevent competitors from entering the market, which is unlawful under the Sherman Act.\textsuperscript{45}

Data on the metastatic breast cancer drug market share owned by various pharmaceutical companies is not freely available. In 2021, Professors Paul Wilcock and Rachel M. Webster briefly discussed the breast cancer drug market, highlighting current and future drugs that are being and will be used to treat the various presentations of the disease.\textsuperscript{46} They discussed that, in 2019, the breast cancer drug market totaled $20.2 billion, and is forecasted to grow nine percent annually to $47.7 billion in 2029, “despite competition from generic and biosimilar agents.”\textsuperscript{47} Wilcock and Webster went on to note that

\begin{itemize}
  \item \textsuperscript{42} Id. at § 1:4.
  \item \textsuperscript{43} WORLD HEALTH ORG., supra note 27, at 27–28.
  \item \textsuperscript{44} Id.
  \item \textsuperscript{45} MILES, supra note 7, at §1:4.
  \item \textsuperscript{47} Id. at 340.
\end{itemize}
CDK4/6 and HER2-targeted agents are expected to maintain their share of 73% of the breast cancer drug market by 2029, accounting for $20 billion and $15 billion, respectively. Even though the authors noted that new drug classes entering the market are expected to diversify treatment options for certain patients, they admitted that this will be constrained for those with certain biomarkers in the broad spectrum of such a biologically individualized disease like metastatic breast cancer, and. Additionally, the authors did not discuss the impact therapy diversification might have on the monopolization of the market, or market share in general.

The fact that the pharmaceutical companies who manufacture metastatic breast cancer drugs hold a monopoly over the market has been argued and discussed for at least the past decade. The metastatic breast cancer market lacks competition to a degree that the small number of companies who manufacture and sell these drugs continue to get away with charging terminal patients exorbitantly high prices to marginally prolong their lives while preventing more meaningful and affordable advancements from being created, and will more than double their profits in the next decade doing so.

B. MAINTAINING THE MONOPOLY

The firms who produce metastatic breast cancer drugs have not only taken illegal acts in their attempts to monopolize the market for this advanced stage of the disease, but, because they were successful, they have also engaged in methods to maintain monopoly power, also in violation of Section 2 of the Sherman Act. In addition to charging high prices, the World Health Organization explained that the monopoly power of cancer drug pharmaceutical companies has allowed them to engage in “market-skimming pricing” for cancer drugs. This method initially sets drug prices as high as possible, then lowers prices over time “to ‘skim the cream’ from customers with lower

48. Id.
49. Id.
50. See generally Siddiqui & Rajkumar, supra note 3 (article published in 2012).
51. WORLD HEALTH ORG., supra note 27, at 25.
52. MILES, supra note 7, § 6:1.
willingness to pay.” Furthermore, maintaining the highly concentrated drug market disincentivizes meaningful new drug development, arguably the most harmful effect of these firms’s actions.

As articulated by Doctors Mustaqeem Siddiqui and S. Vincent Rajkumar in *Mayo Clinic Proceedings*, “[n]ew versions of older cancer drugs do not become alternatives that engender true competition for price. Instead, these new versions over time become replacements for older medicines, sustaining the monopoly.”

It makes sense intuitively that new versions of life-sustaining medications for incurable diseases such as metastatic cancer would replace their older counterparts, as our knowledge of these diseases is constantly growing and evolving. However, the problem is rather that the firms at issue are, arguably, choosing not to develop metastatic breast cancer drugs that offer meaningful improvements for patients’ health. The fact of the matter is, currently, “newer drugs are not associated with greater survival than older drugs.”

Since 2009, the annual number of cancer drugs approved by the FDA has increased significantly, from eight, to fifty-seven in 2020. Yet, only 16% of the 332 approvals throughout the decade were based on new drug approaches. Some experts argue that the financial incentives to neglect to develop meaningfully improved drugs “divert research and drug development from true innovation” and, as a result, ultimately harm patients. Former FDA deputy commissioner and NIH oncologist Anand Shah noted, “Patients need choices and the marketplace needs competition, but unfortunately so much of drug development is redundant without a meaningful improvement in outcomes or lower costs for patients.”

Producers of breast cancer drugs who keep prices high and neglect to develop treatment options that will meaningfully

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53. WORLD HEALTH ORG., supra note 27, at 30.
54. Siddiqui & Rajkumar, supra note 3, at 938.
55. Howard et al., supra note 1, at 148.
57. Id. at 3.
58. Id. at 6.
extend the lives of terminally ill patients argue that regulating the industry by lowering prices will destroy innovation and lead to worse outcomes for patients. Indeed, this argument is made by pharmaceutical companies every time the cost of healthcare and medications in the United States is criticized. The individuals at the top of these firms insist that, considering research and development costs, lowering drug prices will extinguish funding, motivation to innovate, and ability to produce better treatments and technologies. In reality, the data shows that linking actual research and development costs to cancer medication prices, after accounting for all of the public contributions that go into drug discovery, would result in a sizeable decrease in cost of many of the medications.\textsuperscript{60} In addition, because profits from these medications are so high, they may, in fact, be stifling innovation due to investment distortion.\textsuperscript{61} As a result, lowering the prices of cancer drugs would be more beneficial to innovation than pharmaceutical companies’ current practices.\textsuperscript{62}

The cost of cancer drugs, even when adjusted for inflation, has substantially increased over time.\textsuperscript{63} Fairly little information is available about the process by which newly FDA-approved, branded drugs are priced and, considering that advancements in the treatment of metastatic breast cancer may require more funds to be invested to develop new drugs, it is possible that costs for pharmaceutical manufacturers have increased over time.\textsuperscript{64} However, due to a lack of data, costs cannot be evaluated empirically.\textsuperscript{65} Not only is this lack of knowledge about and transparency within the breast cancer industry alarming, the costs of research, development, and drug pricing methodologies are not the only parts of the process the public is in the dark about.

We similarly do not know enough about one of the most important parts of breast cancer research and, truly, medical research in general – clinical trials. Dr. Viale, a leading breast cancer pathologist involved in the International Breast Cancer Study Group, explained that in the mid-90s, any and all breast

\textsuperscript{60} World Health Org., \textit{supra} note 27, at 83.
\textsuperscript{61} \textit{Id}.
\textsuperscript{62} \textit{Id}.
\textsuperscript{63} Howard et al., \textit{supra} note 1, at 153.
\textsuperscript{64} \textit{Id} at 140–41, 157.
\textsuperscript{65} \textit{Id}.
cancer patients were considered eligible to join clinical trials. A few years later, when researchers realized the biological individuality of the disease, they began to tailor the studies to specific breast cancer types and presentations. As a result, breast cancer patients “enrolled in tailored clinical trials for a disease that was not theirs.” Professor Alberto Cambrosio and peers wrote in 2017 that “[t]his could have had potentially dire consequences, including not only the selection of the ‘wrong’ patients for a given clinical trial, but also the production of questionable results, undermining future therapeutic advice.”

The point here is not to call into question the ethics and validity of breast cancer research or clinical trials. However, the lack of transparency in the form of publicly-accessible information, considering the evidence that is ascertainable that the pharmaceutical companies who manufacture metastatic breast cancer drugs are violating federal antitrust laws in the United States, is alarming.

In 2019, Doctors Jinani Jayasekera and Jeanne Mandelblatt conducted a systematic review of the cost-effectiveness of breast cancer treatment. In eighteen articles estimating the cost-effectiveness of therapies in the metastatic setting, nearly half of seventy interventions found that treatment was not cost-effective due to higher drug costs and small health gains. The researchers also observed that “analyses with industry relationships or sponsorship were more likely to show favorable cost-effectiveness ratios compared with similar studies without industry relationships,” suggesting the potential for biased assessments of the cost of metastatic treatment. Overall, the review found what this Note has espoused thus far – new treatments for metastatic breast cancer come at the expense of high research and development costs,

67. Id.
68. Id.
69. Id. at 169.
71. Id. at 344.
72. Id. at 347.
“where dollars allocated to drugs that show minimal benefit are not being spent on gains elsewhere.”

Further evidence that metastatic breast cancer drug manufacturers might be disincentivized from developing meaningful new treatments for the disease is shown by current data on the effectiveness of precision oncology. Multiple trials have concluded that only a small percentage of patients with advanced stages of cancer benefit from genome-informed therapy. Further, the magnitude of clinical benefit that can be attributed to biomarker matched interventions is a mere matter of additional months of life. Even though these limitations of precision oncology might, in part, be attributable to causes that can be remedied and improved, more than twenty years have passed since precision oncology-related approaches were first heralded to yield substantial health benefits for patients. Its effect on clinical decision-making, namely, “increased reliance on bio-plausibility and de-evaluation of evidence,” is reflected in oncological practice by resulting deregulation and “reduced evidence requirements for marked authorisation of novel drugs, including increased reliance on single arm studies as well as poorly validated surrogate endpoints.” This “increasing distance between the expectations and realisations of precision oncology” only contributes to the increasing cost of metastatic breast cancer treatment. Other researchers also note that “[r]eliance on uncertain genetic tests can result not only in wasted resources but also in harm to patients,” including unnecessary treatments and procedures undergone in an attempt to mitigate one’s individual risk of cancer.

C. UNFAIR METHODS OF COMPETITION

Under the Federal Trade Commission Act, the FTC is empowered to prevent unfair methods of competition, determine whether conduct constitutes such, and prevent conduct that

73. Id.
74. Caroline Engen, Introduction to the Imaginary of Precision Oncology, 5 HUM. PERSPS. IN HEALTH SCIS. & TECH. 17, 21 (2022).
75. Id.
76. Id.
77. Id. at 23–24.
78. Id. at 24.
79. Sara Green et al., Plastic Diagnostics: The Remaking of Disease and Evidence in Personalized Medicine, 304 SOC. SCI. & MED., July 2022, at 5.
violates the spirit of the Sherman and Clayton Acts.\textsuperscript{80} Engaging in exclusionary or predatory conduct to prevent competition is also explicitly illegal under federal antitrust law.\textsuperscript{81} Over the past two decades, several of the biggest players in the metastatic breast cancer pharmaceutical industry have engaged in these unfair methods of competition that has spurred action by plaintiffs and the FTC alike.

Bristol-Myers Squibb’s trademarking of the word “taxol,” a research term created by publicly-funded scientists and accepted chemical name, for its metastatic breast cancer drug, and its subsequent attempts to eradicate competitors engaging in metastatic breast cancer research, spurred several suits in the early 2000s.\textsuperscript{82} The FTC, in particular, alleged that the firm’s conduct was anticompetitive in violation of antitrust laws, with the clear goal of “delay[ing] generic competition and maintain[ing] its monopoly” over its highly profitable drugs.\textsuperscript{83} At around the same time, Zeneca and Barr Pharmaceuticals entered into a reverse payment settlement agreement to prevent a generic drug from coming to the market.\textsuperscript{84} Although the suit was ultimately dismissed, the United States Supreme Court held in 2013 that such agreements are not immune from antitrust law and have the potential to bring serious anticompetitive effects.\textsuperscript{85} In 2009, the FTC also filed a complaint when Teva Pharmaceutical Industries’ acquisition of Barr Pharmaceuticals would have resulted in the same company owning seventy-three percent of the generic tamoxifen market, a major metastatic breast cancer drug.\textsuperscript{86}

Case law on potential antitrust violations in the breast cancer drug market is sparse. Considering the lack of competition in the industry, coupled with the ever-increasing profits of its players, it is highly likely that antitrust laws are underenforced here. The three aforementioned practices – potentially invalid patents and abusive litigation, reverse payment settlements, and mergers and acquisitions – are likely

\begin{footnotes}
\item[80] MILES, supra note 7, at § 6:13.
\item[81] Id. at § 1:4.
\item[82] Duffin, supra note 14, at 10–11; Singer et al., supra note 17, at 1, 10.
\item[83] Singer et al., supra note 17, at 10.
\item[84] In re Tamoxifen Citrate Antitrust Litig., 222 F. Supp. 2d 326, 328 (E.D.N.Y. 2002).
\item[86] Singer et al., supra note 17, at 45–46.
\end{footnotes}
not the only methods the pharmaceutical companies at issue have utilized to maintain their monopoly over the market. In addition to the likely underenforcement of antitrust law violations resulting from these more explicit practices, the previously discussed practices disincentivizing the development of new treatments that would provide meaningful improvements for breast cancer patients, as well as other more subtle practices that may violate the spirit of United States antitrust laws, may well be occurring and should be investigated. Terminal breast cancer patients are harmed and will continue to be by the anticompetitive and monopolistic practices these pharmaceutical companies have been engaging in for decades. As this Note explains, the extent of the high prices of metastatic breast cancer drugs is not inherent to or necessary for the health of the industry. Neither is the fact that new branded drugs only offer marginal improvements from their older counterparts in terms of prolonging life. These characteristics of the metastatic breast cancer drug industry are the result of choices made by the firms who manufacture these drugs, choices that are anticompetitive and in violation of United States antitrust laws.

Considering both the FTC’s and DOJ’s recent commitments and efforts to aggressively enforce federal antitrust laws under the Biden Administration, the urgent recommendation of this Note to investigate and halt breast cancer drug pharmaceutical companies’ violations of these laws is especially appropriate.\textsuperscript{87} President Biden’s July 2021 Executive Order on Competition confirmed that the central goal of his administration to ensure that antitrust laws in the U.S. are strongly enforced.\textsuperscript{88} Although the call for stronger antitrust enforcement was economy-wide, the Executive Order specifically highlighted healthcare and prescription drugs as a sector of concern.\textsuperscript{89} In November of 2022, the FTC released a policy statement regarding the scope of unfair methods of competition under Section 5 of the Federal Trade Commission Act.\textsuperscript{90} The Commission cited numerous

\textsuperscript{88} Id.
\textsuperscript{89} Id.
\textsuperscript{90} FED. TRADE COM’N, No. P221202, POLICY STATEMENT REGARDING THE SCOPE OF UNFAIR METHODS OF COMPETITION UNDER SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT (2022).
decisions of the Supreme Court in iterating that Section 5
“reaches beyond the Sherman and Clayton Acts to encompass
various types of unfair conduct that tend to negatively affect
competitive conditions.”\textsuperscript{91} Further, the Commission detailed
Congress’ “clear aim that ‘unfair methods of competition’ need
not require a showing of current anticompetitive harm and
anticompetitive intent in every case.”\textsuperscript{92} The FTC enjoys the
statutory authority to enforce U.S. antitrust laws in numerous
ways, and has a responsibility to take immediate action in the
metastatic breast cancer pharmaceuticals industry considering
the ever-increasing severity of harm to patients as a result of the
anticompetitive conduct of the firms holding market power.\textsuperscript{93} In
its policy statement, the Commission explained that, in order to
violate Section 5 of the Clayton Act, conduct must be a “method
of competition,” and it must be “unfair,” going “beyond
competition on the merits.”\textsuperscript{94}

\textsuperscript{91} Id. at 1.
\textsuperscript{92} Id. at 4. The Commission goes on to observe:
First, the legislative history is replete with statements to the effect
that Congress wanted the FTC to stop monopolies in their
‘incipiency.’ Requiring the FTC to show current anticompetitive
effects, which are typically seen only after the monopoly has
passed the ‘embryonic’ stage, would undercut Congress’s hope to
prohibit unfair business practices prior to, or near, monopoly
power. In addition, many of the practices listed by Congress as
patently unfair do not automatically carry with them measurable
effects. Second, in considering and rejecting a definition of ‘unfa
methods of competition’ that would have required a showing of
intent, legislators noted that such a requirement would
inappropriately restrict the new provision to the metes and bounds
of the antitrust laws and place an undue burden on the
Commission in proving its cases.

\textsuperscript{93} Id. at 4–5.
\textsuperscript{94} FED. TRADE COMM’N, supra note 90, at 8. As explained by the
Commission,
A method of competition is conduct undertaken by an actor in the
marketplace – as opposed to merely a condition of the marketplace,
not of the respondent’s making … The conduct must implicate
competition, but the relationship can be indirect. For example,
All of the obviously occurring and potential harms to competition discussed in this Note meet both criteria necessary to consider when evaluating whether conduct goes beyond competition on the merits. All four anticompetitive and harmful actions – (1) the lack of meaningful drug development, especially as evidenced through clinical trials; (2) predatory lawsuits against competitors, coupled with reverse payment settlements; (3) potential violations of the essential facilities doctrine; and (4) potential anticompetitive price differentials – are both predatory or involve the use of economic power of a similar nature, and tend to negatively affect competitive conditions by foreclosing or impairing the opportunities of market participants, reducing competition between rivals, limiting choice, and otherwise harming consumers.95

The Commission explicitly confirmed that the second requirement for a finding of negative effects on competitive conditions “does not turn [on] whether the conduct directly caused actual harm in the specific instance at issue,” but instead “examines whether the . . . conduct has a tendency to generate negative consequences; for instance, raising prices, . . . limiting choice, . . . reducing innovation, impairing other market participants, or reducing the likelihood of potential or nascent competition.”96 Further, it noted the lack of case law on acceptable justifications to a prima facie Section 5 unfair methods of competition charge, and that some courts have declined to consider justifications altogether.97 Finally, the FTC offered a non-exhaustive list of conduct that has been found to violate Section 5, including incipient violations of the antitrust laws such as loyalty rebates, tying, and bundling; parallel exclusionary conduct that may cause aggregate harm; conduct

compatibility of regulatory processes that can create or exploit impediments to competition (such as those related to licensing, patents, or standard setting) constitutes a method of competition.

Id. Further, Competition on the merits may include, for example, superior products or services, superior business acumen, truthful marketing and advertising practices, investment in research and development that leads to innovative outputs, or attracting employees and workers through the offering of better employment terms.

Id. at 8–9.
95. Id.
96. Id. at 9–10.
97. Id. at 10.
undertaken with other acts and practices that cumulatively may tend to undermine competitive conditions in the market; inequitable practices that undermine the standard-setting process; mergers or acquisitions that may lessen future competition; conduct resulting in direct evidence of harm, or likely harm, to competition, that does not rely upon market definition; and discriminatory refusals to deal which tend to create or maintain market power.98

D. VIOLATIONS OF THE ESSENTIAL FACILITIES DOCTRINE

Under the essential facilities doctrine, a company “controlling access to or with a monopoly over a facility or trade relationship essential for effective competition (an ‘essential facility’) has an obligation to grant its competitors and potential competitors access to the facility or relationship on reasonable, nondiscriminatory terms if granting access is feasible.”99 The doctrine “imposes liability when one firm, which controls an essential facility, denies a second firm reasonable access to a product or service that the second firm must obtain in order to compete with the first.”100 United States Courts of Appeals have similarly explained that the doctrine imposes an obligation on firms to provide reasonable access to scarce facilities that cannot practically be duplicated by would-be competitors.101 Failure to do so constitutes a unilateral refusal to deal in violation of Section 2 of the Sherman Act.102 The four elements plaintiff competitors would be required to show in order to establish a violation of the essential facilities doctrine are (1) the defendant is a monopolist in control of an essential facility; (2) the plaintiff, as the defendant’s competitor, is unable to reasonably or practically duplicate the essential facility; (3) the defendant has refused to provide the plaintiff access to the essential facility; and (4) it is feasible for the defendant to provide such access.103

98. Id. at 12–16.
101. Id.
102. Id. at 446–47.
103. Aerotec Int’l, Inc. v. Honeywell Int’l, Inc., 836 F.3d 1171, 1185 (9th Cir. 2016) (citing MetroNet Servs. Corp. v. Qwest Corp., 383 F.3d 1124, 1128–29 (9th Cir. 2004)).
Pharmaceutical companies who manufacture metastatic breast cancer drugs, such as Myriad Genetics, have likely violated the essential facilities doctrine. Even after the United States Supreme Court invalidated some of Myriad’s BRCA-related patents in *Association of Molecular Pathology v. Myriad Genetics*, the pharmaceutical company filed lawsuits against seven others alleging infringement of patents the Court had not yet invalidated.\(^\text{104}\) Until November 2004, Myriad contributed to public databases of BRCA mutations; since then, it has withheld data necessary for doctors and researchers to understand BRCA1 and BRCA2 mutations and their effects on breast cancer as proprietary.\(^\text{105}\) As a result, only Myriad can offer the most informative interpretations of individuals’ genetic mutations, holding “a broader monopoly on information that patients and their physicians may obtain about the contents of an individual’s own DNA, including the patient’s own heightened risks of life-threatening disease.”\(^\text{106}\)

Myriad’s withholding of data on BRCA mutations from the rest of the scientific and medical community is a clear violation of the essential facilities doctrine. Considering the aforementioned projections for the breast cancer drug industry over the next decade, potential plaintiffs and the FTC alike would be well advised to investigate other pharmaceutical companies who appear to be in possession of essential data or information about the treatment of the disease that competitors cannot duplicate. Such a request may turn out to be too great of a feat, considering the possibility that potential plaintiffs (competitor pharmaceutical companies) might be hesitant to publicly broadcast their competitors’ refusals to provide access to essential facilities for the reasons discussed in Part II.B. Assuming that competitor pharmaceutical companies want to maintain their market share and profits in what has been established to be a highly concentrated market, a fight to win access to essential facilities may not be worth the effort if profits can soar by other means. Although this is a cynical proposition, it is consistent with the argument made by experts that these companies choose to refrain from making meaningful

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105. Id. at 541.
106. Id.
developments for cancer drugs. In any event, considering the seriousness of violations of this doctrine in an industry with high entry barriers such as metastatic breast cancer research, and the chilling effect on competition this creates, such violations should be investigated by the FTC.

Demonstrating a violation of the essential facilities doctrine requires meeting an incredibly high bar, and the doctrine has traditionally been applied in the context of natural monopolies. Yet, numerous courts have more recently held that the doctrine applies equally to intellectual property and other intangible assets. In *Intergraph Corp. v. Intel Corp.*, the U.S. Court of Appeals for the Federal Circuit held that mandatory access to intellectual property “may be imposed—where the defendant’s refusal to license access to such intellectual property demonstrates anti-competitive intent.” In the pharmaceutical industry, specifically, “[p]atents over upstream gene sequences may block further downstream research and, consequently, adversely impact drug discovery, as many diseases today are known to have genetic origins.” Regarding the doctrine’s requirement that a competitor be unable to reasonably duplicate the essential facility at issue, the inherent high costs of pharmaceutical research and development affecting the financial viability of alternatives to such facilities would be key in the analysis. Further, the patented genes implicated in diseases such as breast cancer are unique because they cannot be designed around in the development of therapeutics.

Patents and intellectual property rights in the breast cancer pharmaceutical industry result in several anticompetitive effects. Patients pay higher prices than they would in a competitive market, firms neglect to market more comprehensive and efficient methods of genetic testing, and competitors are prevented from developing improved therapies. Regarding the regulatory burden: “Without access

107. Pitofsky et al., supra note 100, at 452–53.
108. Id. at 456 (citing *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1356, 1363 (Fed Cir. 1999)).
110. Id. at 95.
112. See id. at 438–39.
to alleged trade secret biologic resources and production information, the approval of biosimilars can take longer, leading to higher prices for originator products. This ultimately drives up the cost of health care and reduces patients’ access to critical, cutting-edge treatments for conditions, including...cancer.”113 Apart from patent and intellectual property concerns, pharmaceutical companies have also invoked trade secret protections for financial information constituting drug pricing data, fueling high drug prices and preventing ascertainment of potential violations of antitrust laws.114

E. ANTICOMPETITIVE PRICE DIFFERENTIALS

Finally, Section 2(a) of the Clayton Act’s prohibition on selling to different customers at different prices if doing so results in anticompetitive effects is another opportunity for the government to prevent pharmaceutical companies who manufacture metastatic breast cancer drugs from continuing to violate federal antitrust laws. Confidential discounts or rebates, pricing according to buyers’ willingness to pay, and agreements that keep pricing strategy and methodology completely confidential are all causes for concern with regard to Section 2(a), especially considering the projected growth of the industry over the next decade.115 Wilcock and Webster explained that the sales growth will be fueled by “[t]he continued uptake and expanded use of CDK4/6 inhibitors and entry of 14 premium-priced agents, including therapies approved in 2019 or 2020 (trastuzumab deruxtecan, tucatinib, margetuximab, atezolizumab, pembrolizumab, alpelisib and sacituzumab govitecan).”116 They go on to detail the following:

By 2029, the CDK4/6 and HER2-targeted agents are expected to maintain their share (73%) of breast cancer sales, attributing for approximately $20 billion and $15 billion, respectively. Trastuzumab deruxtecan is expected to become the top-selling HER2-targeted drug owing to its anticipated broad use for HER2-positive, HR-positive/HER2-negative and triple-negative cancers and its long treatment duration. The anticipated label expansion of two CDK4/6 inhibitors (abemaciclib and ribociclib) for early-stage HR-positive/HER2-negative...
breast cancer will also drive sales, adding $14 billion in 2029 (69% of
drug class sales) in our forecast, with abemaciclib contributing $13
billion (94%) of adjuvant sales.\footnote{Id.}

Putting into perspective the numbers corresponding with
the sale of metastatic breast cancer drugs over the next decade,
coupled with the relatively few number of drugs being sold,
metastatic breast cancer patients deserve federal antitrust law
enforcement efforts targeting anticompetitive price differentials.

The assertion that these firms are violating Section 2(a) of
the Clayton Act is not being pulled out of thin air. The World
Health Organization itself has noted that “like a monopolist,
[these] pharmaceutical companies often adopt price
discrimination . . . but refer to it as ‘tiered or differential
pricing.’”\footnote{WORLD HEALTH ORG., supra note 27, at 30.} As previously discussed, researchers have explained
how oncologists derive more than fifty percent of their revenues
from administering cancer drugs through buy and bill
reimbursement systems that link drug choices to financial
incentives.\footnote{Howard et al., supra note 1, at 144; Epstein & Johnson, supra note 31, at 286.}

Such a system could lead to perverse financial incentives for those in whom terminally ill breast cancer
patients have placed their ultimate trust. The negotiations and,
ultimately, the agreements made between pharmaceutical
companies and physicians to ensure that these physicians
administer the drugs most profitable for them, are undoubtedly
no different from each other to the extent that the resulting
effects are anticompetitive, as physicians may be inclined to
choose drugs with high profit margins for themselves and their
practices. In a 2019 systematic review evaluating eighteen
studies to determine whether the financial incentives
represented by oncology reimbursement policies affect physician
practice patterns, almost all had at least a moderate risk of bias.\footnote{Aaron P. Mitchell et al., Association Between Reimbursement Incentives and Physician Practice in Oncology: A Systematic Review, 5 JAMA ONCOLOGY 893, 893 (2019).} The review’s findings suggested that “some oncologists
may, in certain circumstances, alter treatment recommendations based on personal revenue considerations.”\footnote{Id.} Furthermore, evidence suggests that implementing a different
model for treating metastatic breast cancer, such as a pay-for-
performance reimbursement model, would increase the use of evidence-based drugs and, consequently, improve the quality of care.\textsuperscript{122}

CONCLUSION

The metastatic breast cancer drug industry provides a unique view into how the enforcement of federal antitrust laws can be a life or death matter. Breast cancer is among the most common cancers in the world, and those who are ill with the metastasized disease are terminal patients. Their treatment options are limited and must be used consecutively or simultaneously. On top of it all, the cost of their life-prolonging medications is extremely, devastatingly high. Simply looking at the HHI score showing a highly concentrated market makes it crystal clear that monopolization plagues the metastatic breast cancer drug industry. The newer, branded drugs consistently coming to market are not associated with greater survival rates than their older counterparts. Experts have concluded that much of breast cancer drug development is redundant and lacks meaningful improvement, demonstrating that these pharmaceutical companies may be working to maintain their monopoly power, in violation of the law. Furthermore, anticompetitive agreements and mergers and acquisitions among competitor firms in the industry, predatory practices and patents that likely violate the essential facilities doctrine, and anticompetitive differential pricing are all areas of the industry in need of investigation to ensure that federal antitrust laws are being enforced.

This Note has detailed the relatively little that is publicly available regarding the metastatic breast cancer drug industry in the United States, how profitable it has been, and how profitable it will continue to be over the next decade. It has demonstrated how several key facets of the industry seem to clearly violate the most basic tenets of federal antitrust laws. The bottom line is, all evidence publicly available suggests that the metastatic breast cancer drug market is not a competitive one and, although entry barriers to the market may be

understandably high considering the time, expense, and complexity that goes into developing drugs that target highly biologically-individualized diseases, they may not be so high as to warrant the highly centralized nature of the market. Furthermore, what may be even more concerning are the practices in which these firms engage to ensure that the industry does not become more competitive. Breast cancer patients would greatly benefit from the Federal Trade Commission of the United States, other investigators of federal antitrust violations, and potential plaintiffs investigating these firms. Their lives depend on it.