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With Challenge of Illumina-Grail Merger, Biden Antitrust Policy Claims its First Victim: Cancer Patients

by Abbott B. Lipsky, Jr.

The air is already thick—and getting thicker almost daily—with lawsuits and proposed legislation intended to address an ever-lengthening list of grievances regarding alleged wrongdoing by leading technology firms and various other laments about competition in the US economy. The complaints are based on a wide variety of themes, ranging from political bias, censorship and data privacy breaches to the competitive risks and benefits of practices such as vertical acquisitions, "self-preferencing" and acquisitions of "nascent competitors." These complaints have given rise to demands for stricter treatment of such practices under antitrust law, by extension of case precedent or statutory amendment.

As the antitrust community debates the merits of these complaints and their alleged solutions, the gloves are off between supporters of the prevailing economics-based case-by-case approach to antitrust and the "Neo-Brandeisians." The economics-based approach is supported by a broad consensus (among scholars of law and economics, enforcers, practitioners and courts) that evolved after a long period in which *per se* rules, structural presumptions and vague political themes dominated antitrust interpretation. By contrast, the Neo-Brandeisians would discard the case-by-case economics-based approach and restore the *per se*/structuralist/political enforcement model, rebuking a half century of scholarship and common-law evolution. Although the present antitrust ferment is motivated primarily by concerns about a handful of extraordinarily successful and transformational firms such as Amazon, Apple, Facebook and Google, many of the revanchist proposals would affect the entire range of economic activity that is subject to antitrust.

Based on limited but powerful evidence thus far, the Biden antitrust program is already cast firmly in the Neo-Brandeisian mode. Two of the most visible and ardent advocates for the *per se*/structuralist/political approach—Columbia Law School Professors Tim Wu and Lina Khan—were the first to be appointed to relevant senior policy positions (Wu to the National Economic Council as Special Assistant to the President for Technology and Competition Policy, Khan as Chair of the FTC). Although not necessarily a direct reflection of White House instruction, it was striking that the Biden-appointed acting FTC Chair, Rebecca Kelly Slaughter, condemned a recent Supreme Court decision in sharp terms: "In *AMG Capital* [*v. FTC*][1], the Supreme Court ruled in favor of scam artists and dishonest corporations, leaving average Americans to pay for illegal behavior . . .."[2] This seemed a confrontational response to a Supreme Court decision that was unanimous, widely anticipated, and based on an issue of statutory construction and not on the relative standing of "scam artists and dishonest corporations" as distinct from "average Americans." Within weeks of Khan's arrival as FTC Chair, the Commission adopted on a 3-2

[1] *AMG Capital Mgmt., LLC v. FTC*, No. 19-508 (U.S. Apr. 22, 2021).
[2] Federal Trade Commission press release, Statement by FTC Acting Chairwoman Rebecca Kelly Slaughter on the U.S. Supreme Court Ruling in AMG Capital Management LLC v. FTC (Apr. 22, 2021).

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partisan vote a series of resolutions signaling a determination by the Democrat majority to implement a long list of measures intended to condition the FTC's legal and procedural environment to facilitate enforcement.[3] Commissioner Wilson's dissent to those actions seems to indicate that there was little if any effort by the Chair or Democrat majority to reach consensus with the two Republican commissioners, or even allow full consideration (including public notice and comment, or even review by the FTC's own professional staff) of the actions.[4]

With the unmistakable signals of radical change emitted by the Biden appointments and the early actions by its enforcers, the antitrust community is scanning the output of the agencies for further tangible indications of the true character and extent of the new approach. A pending FTC challenge to the proposed acquisition of Grail, Inc. by Illumina, Inc., is a good specimen for study, as it reflects several of the main themes of contention in the current economics/Neo-Brandeisian dialectic. The case involves a vertical acquisition in a dynamic biotechnology sector between a leading innovator and a promising start-up created earlier by the acquiring firm and then spun off to develop a breakthrough application of its technology. The start-up firm is still at the proof-of-concept stage and lacks significant revenue from any commercial offering.

The Commission appears to have succeeded in holding up the deal (at least for the moment), relying on several procedural gimmicks and without having to convince any court of the merits of its antitrust concerns, which appear doubtful at best. As explained below, the Commission has thereby stimulated concern regarding the current and future direction of both substantive and procedural aspects of its antitrust enforcement program. The matter also provides a clear example of how proposed solutions cooked up with one set of actors and problems in mind (digital platforms and the growing list of complaints they evoke) can cause serious unintended adverse consequences if applied to other situations governed by well-considered analytical principles—in this case, a classic vertical transaction, apparently intended to allow related parties to perfect and commercialize a profound breakthrough in cancer detection.

The would-be buyer Illumina, founded in 1998 in San Diego, is the leading supplier of systems for genetic sequencing, specifically next-generation sequencing or "NGS."[5] Illumina's NGS systems are said to have reduced the cost of human gene sequencing by a factor of 1,000, bringing the technology within practical reach of many academic and clinical research institutions, pharmaceutical companies, and other life-science firms. The target, Grail, was formed by Illumina in 2015 and spun off in 2016, with Illumina retaining 20% equity interest (since reduced to about 14%). Grail, headquartered in Menlo Park, was launched by Illumina to develop applications of Illumina's NGS systems to create blood tests that would detect cancers at early stages—before they produce evident symptoms or otherwise become detectable.

Grail raised significant additional financing from outside sources, including Jeff Bezos and Bill Gates. Grail has now developed a test known as "Galleri," which, according to Grail's website, "has shown the ability to detect multiple types of cancers through a single blood draw. Most of these cancers cannot be detected through current screening paradigms. When cancer signal was detected, the Galleri test localized the cancer signal with high accuracy, helping inform next steps to diagnosis."[6] Galleri is a contender for future leadership in what the Commission's Complaint describes as multi-cancer early

[3] Federal Trade Commission press release, FTC Authorizes Investigations into Key Enforcement Priorities (July 1, 2021). The Commission simultaneously rescinded the FTC's 2015 "Statement of Principles Regarding Enforcement of FTC Act as a Competition Statute." Federal Trade Commission press release, FTC Rescinds 2015 Policy that Limited Its Enforcement Ability Under the FTC Act (July 1, 2021).

[4] Dissenting Statement of Commissioner Christine S. Wilson, Open Commission Meeting on July 1, 2021: Made in USA Final Rule, Section 18 Rulemaking Procedures, Statement of Enforcement Principles Regarding 'Unfair Methods of Competition' Under Section 5 of the FTC Act (2015), Enforcement Investigations/Omnibuses Procedures (July 1, 2021).

[5] FTC Complaint (Redacted-Public Version), In the Matter of Illumina, Inc., and GRAIL, Inc., Docket No. 9401 (Mar. 30, 2021).

[6] GRAIL, Inc., Our Products: Galleri GRAIL's multi-cancer early detection test (last accessed July 7, 2021).

detection (MCED).[7] According to the FTC's complaint,[8] Grail "is racing against several other firms to develop and ultimately commercialize this revolutionary technology." As there are no marketable MCED tests available at present, the Complaint is speculating that such a market might emerge.

Like Illumina's breakthrough NGS technology, according to the Commission, "Grail, its rivals, and others in the industry view MCED tests as a major advancement in the war on cancer."[9] The FTC's concern about the likely competitive effect of the transaction is stated as follows:

> As the only supplier of a critical input, Illumina already possesses the ability to foreclose or disadvantage Grail's MCED rivals. Illumina has several tools available that it could use to impede the competitiveness of any MCED test developer. If Illumina determined it would maximize its profits by limiting the competitiveness of an MCED test that posed a threat to Grail's Galleri business, among other things, it could (1) raise the test developer's prices for NGS instruments and consumables, (2) impede the rival's research and development efforts by denying important technical assistance and other proprietary information needed to obtain FDA approval or design a commercially successful MCED test, or (3) refuse or delay the execution of a license agreement required to sell distributed in vitro diagnostic ('IVD') versions of the test (or offer the license on terms that would restrict the competitiveness of the rival's IVD test).
>
> If the Acquisition is consummated, Illumina will gain the incentive to foreclose or disadvantage firms that pose a significant competitive threat to Grail and to limit the competitiveness of any MCED product that Respondents expect to compete closely with Galleri. While Illumina currently benefits from selling NGS platforms and consumables to all MCED test developers, if the Acquisition is consummated, instead of realizing profits only from the sale of NGS platforms and consumables, Illumina stands to profit significantly from sales of Grail's MCED test.[10]

On March 30, the FTC announced a unanimous vote to issue the administrative complaint challenging the transaction. Following its usual practice, it authorized staff to seek a preliminary injunction in federal district court blocking the transaction pending resolution of the Commission's own administrative proceeding. From that point forward, however, usual practice seems to have gone out the window. On May 20 the FTC announced its intention to request the court to dismiss its case seeking an injunction, based on the stated rationale that the European Commission had initiated a separate antitrust review of the transaction under the European Union Merger Regulation (EUMR).[11] This would have the effect of prohibiting the transaction until such time as the European Commission proceeding is resolved. The court granted the Commission's request over the parties' objections.[12]

Given that Grail is a start-up enterprise with minimal revenue, one may question how the European Commission managed to assert jurisdiction, given that the EUMR applies (with narrow exceptions) only to transactions of "Community dimension," as defined by various non-trivial thresholds for turnover within the EU and in particular Member States. The Commission claims to rely on a jurisdictional exception contained in Article 22 of the EUMR, the so-called "Dutch Clause." This reliance, however, presents a distinct puzzle in itself. Article 22 was enacted as part of the EUMR to allow Member States like the Netherlands—which at the time had no institutional capacity to review mergers on competition grounds—to request European Commission review of transactions, even where "Community dimension"

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[7] FTC Complaint ¶1.
[8] FTC Complaint ¶4.
[9] *Id.*
[10] FTC Complaint ¶¶ 11, 12.
[11] Council Regulation 139/2004, O.J. (L 24) 1–22 (EC).
[12] Judgment of June 1, 2021, *FTC v. Illumina Inc.*, Civ. Ac. No. 21-CV-00800-CAB-BGS (June 1, 2021).

thresholds were not met. Because the idea of Commission review of transactions lacking any impact on the Single Market conflicts with the fundamental EU concept of subsidiarity, Article 22 has thus far been treated as a disfavored device.[13]

In a September 11, 2020 speech, EU Executive Vice President and Competition Commissioner Margrethe Vestager called out the previous policy only to reverse it. She declared, "We plan to start accepting referrals from national competition authorities of mergers that are worth reviewing at the EU level—whether or not those authorities had the power to review the case themselves." [14] In effect, this converted Article 22 into a device allowing Commission review of any transaction "worth reviewing" that would otherwise escape its authority—including acquisitions of "nascent competitors", i.e., firms thought to have significant future prospects but little or no market presence (sales, revenue and/or output). Without other official preliminaries of any kind, on February 19, 2021, the European Commission invited Member State antitrust agencies to request a referral to the EC of the Illumina/Grail transaction under the Dutch Clause.[15] The French antitrust agency obliged by submitting such a request on March 9, soon joined by the competition agencies of Belgium, Greece, Iceland, the Netherlands and Norway. On March 26, 2021, apparently without providing any opportunity for public input, the Commission issued a "guidance paper" to place the new policy into immediate effect. The Commission then accepted the self-generated referrals of the Illumina/Grail transaction on April 20 and ordered the parties to submit a standard notification pursuant to the EUMR.[16]

Given Grail's minimal commercial revenue and lack of competitive presence in the European Union, it is difficult to understand how the Commission or any EU Member State could have legitimate competitive concerns regarding the transaction.[17] Nevertheless, it appears that some chain of events—possibly inspired by the FTC, a third-party complaint, or perhaps both—resulted in the EC's sudden policy reversal, and its successful solicitation from Member States of an Article 22 reference. The parties have challenged the Commission's legal basis for the proceeding, but they have filed the requested notification and are simultaneously cooperating with the Commission in seeking a resolution of any issues that the Commission might bring forward.[18]

Aside from its direct negative impact—jerry-rigging a sudden new procedural roadblock to the transaction just as the month's-long FTC Hart-Scott-Rodino review finally concluded—the Commission's unprecedented actions also served as a cover for the FTC's own questionable procedural moves in this case. In merger cases, routing an FTC suit for judicial injunction back into the Commission's administrative process—like the European Commission's Article 22 device—has long been regarded as a

[13] "Under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the [European] Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level." Treaty on European Union, art. 5, cl. 3, Feb. 07, 1992, O.J. 326/18.

[14] Margrethe Vestager, The Future of EU Merger Control, Speech at the International Bar Association 24th Annual Competition Conference (Sept. 11, 2020).

[15] Gavin Bushnell, How Illumina-ting: the EU Merger Regulation and the brutal operation of power under Article 22 EUMR, Wolters Kluwer, Kluwer Competition Law Blog (Apr. 20, 2021).

[16] European Commission Press Release, Daily News 20 / 04 / 2021 (Apr. 20, 2021); *see also* Bertille Gauthier, The European Commission opens a review of Illumina's acquisition of Grail under the procedure of Article 22 of the 2004 Merger Regulation, Autorité de la Concurrence (Apr. 20, 2021).

[17] Although not a binding legal constraint on the assertion of jurisdiction to require prenotification and approval of structural transactions, the International Competition Network Recommended Practices for Merger Notification and Review Procedures, ¶II.C., provides:

> Determination of a transaction's [required jurisdictional] nexus to the reviewing jurisdiction should be based on activities within that jurisdiction as measured by reference to the activities of at least two parties to the transaction in the local territory and/or by reference to the activities of the acquired business in the jurisdiction.

[18] Illumina Press Release, Illumina Files Action for Annulment of European Commission's Decision Asserting Jurisdiction to Review GRAIL Acquisition (Apr. 29, 2021).

disfavored procedure.[19] The FTC has sometimes exercised its unique authority to review mergers through administrative litigation, even where it has pursued litigation to obtain a judicial injunction against the transaction—successfully or unsuccessfully.[20] Unlike merger litigation in federal court, administrative litigation can last many years—nine years in one merger case[21]—allowing the Commission to threaten parties with the cost, delay and complexity of extended proceedings and thereby enhancing its ability to discourage, kill or require substantial revisions to transactions even where the Commission's antitrust allegations are weak.

Responding to concerns about this type of abuse, in 1995 the FTC adopted a rule suggesting that its default approach to merger cases would be to take such challenges to court and live with the result, foregoing the opportunity to bludgeon the parties with threats of interminable administrative litigation. Although the Commission briefly wavered in applying this policy and actually repealed the applicable rule in 2008 (reinstated in 2015 as corrective legislation began to work its way through Congress), its reversion to the administrative approach in the Illumina/Grail matter is without recent precedent, and flouts the concerns expressed about the FTC's unique procedural options.[22] In its motion to dismiss its complaint challenging Illumina/Grail, the FTC invoked the pendency of the European Commission investigation as the main rationale. This "tag-team" approach of the US and European authorities has the potential for profound disruption of the process of global review of structural transactions, forcing parties to confront the possibility of sequential end-to-end proceedings first in the US and then in Europe. With scores of jurisdictions requiring merger prenotification and clearance and/or approval, the notion of allowing *sequential* merger reviews by different jurisdictions, as in this case, would lead to massive delays for transactions subject to review in multiple jurisdictions. With the European Commission essentially claiming jurisdiction over any merger (provided it can precipitate an Article 22 reference request by any Member State)—regardless of the size of the parties or whether the parties have any commercial presence in the European Union—acceptance of this pattern of "cooperation" between

[19] If the Commission fails to obtain an injunction, continuing administrative litigation puts the Commission in the position of relitigating determinations made by Article III courts. While the matter may not satisfy preclusion tests such as res judicata or collateral estoppel that would rule out such a move, the costs of an entirely separate FTC proceeding in such circumstances are likely to exceed any potential benefit by a wide margin. This is especially so where the court considering the preliminary relief request determines the merits of granting a permanent injunction. Alternatively, when the Commission wins an injunction, following up with administrative litigation allows the Commission to "pile on" its success in court. Again, costs are likely to exceed benefits by a substantial margin. Aside from the disadvantages of Commission proceedings in these two specific situations, there is an independent concern that differences between FTC and Antitrust Division procedural options and applicable legal standards create an arbitrary random and unpredictable element in the disposition of mergers, depending on whether the FTC or Antitrust Division happens to investigate any particular transaction.

[20] In the usual FTC administrative litigation, an Administrative Law Judge conducts a trial-type hearing and renders an Initial Decision, which is then subject to *de novo* Commission review. The Commission decision is then subject to review in an appropriate U.S. Court of Appeals. The Commission has a pronounced tendency to uphold its own complaints, and appellate review is generally conducted under standards deferential to the Commission. This contrasts with procedures followed by the Antitrust Division of the Department of Justice, which involve trial before a district court, subject to appeal to a U.S. Court of Appeals. The court conducts a trial with the usual procedural protections of federal civil litigation and assesses the Division's caselaw and facts—as an independent Article III tribunal. Lacking any administrative option comparable to that of the FTC, the Antitrust Division conducts merger cases as a litigant before the courts, and therefore does not generally receive any special deference.

[21] In re: Coca-Cola Co., FTC Docket 9207. The transaction was announced in 1986. The FTC administrative proceeding challenging the transaction was not resolved until 1995. *See* FTC Press Release, Coca-Cola Company (May 18, 1995), available at https://www.ftc.gov/news-events/press-releases/1995/05/coca-cola-company. During this nine-year period an ALJ hearing was conducted, an initial decision was rendered, the Commission reviewed the decision and issued an order prohibiting the long-dead transaction and imposing other relief, and the parties settled while in the initial stages of appellate review.

[22] For a detailed discussion of the history and evolution of the FTC's "Pitofsky rule" and its other policy guidance regarding use of administrative litigation in merger cases, *see* Abbott B. Lipsky, Jr., Testimony on S. 2102, the "Standard Merger and Acquisition Reviews Through Equal Rules Act of 2015," (Oct. 7, 2015).

the two agencies could lead to major delays, burdens and complexity in the process of international merger clearance. The sequential approach constitutes multijurisdictional cooperation to obstruct, not cooperation to coordinate and reduce the costs and uncertainties of multijurisdictional merger review.

Does the FTC's substantive concern with the Illumina/Grail transaction justify such extraordinary procedural maneuvering? To the contrary: To begin with, the case is a pure vertical transaction, with a total absence of competition between the parties, and with many clear reasons for vertical cooperation between them. As the Commission's Complaint acknowledges, Grail was created as a subsidiary of Illumina for the specific purpose of exploring potential applications of Illumina's breakthrough NGS technology to early cancer detection. Grail was then partially spun out from under full Illumina ownership and financed from several independent sources, with Illumina maintaining a substantial minority ownership interest. Grail was launched based on its access to Illumina's NGS technology and systems, and the potential benefits of cooperation between the parties in perfecting MCED technologies and products—including the long and complex process of obtaining regulatory approval—are obvious.

The evolution of the Illumina/Grail relationship illustrates the typical working-out of a classic and uncontroversial issue in any business organization—make or buy? Should a manufacturer integrate "upstream" to supply its own raw materials, or purchase from independent suppliers? Should the manufacturer integrate "downstream" to engage in its own processing, wholesaling and retailing? Or should it rely on independent processors, wholesalers and retailers? In making such decisions, firms have fundamental incentives aligned with maximizing the success of their market offerings. They will seek to undertake themselves ("make") or call forth from others ("buy") and organize the entire range of functions and activities (self-supplied or procured from independent sources) that will allow the best opportunity for growth and competitive success. This is why vertical mergers have been of antitrust concern only in the rarest cases. The history of the Illumina/Grail relationship, including the acquisition agreement, is a common illustration of the classic working-out of vertical relationships that occurs in thousands of different instances in myriad economic sectors every year.

The FTC Complaint focuses on Illumina's strong position in the supply of NGS systems, and its resulting ability to control the terms and conditions on which downstream firms applying Illumina technology may obtain access to such systems. This is not, never has been, and should not become a legitimate basis for an antitrust complaint against downstream integration by a firm with a superior technology. The fact that Illumina controls the terms and conditions for granting access to its own products and technology is inherent in its identity as a distinct business entity. Unless the FTC proposes to break up Illumina or to regulate the prices, terms and conditions of its commercial offerings—possibilities that would have to be described as truly radical departures from the basic traditions of economics-based antitrust law—blocking the Grail acquisition will not alter Illumina's ability to control the prices, terms and conditions on which Illumina's own offerings are made available to the market. Although one can imagine scenarios in which Illumina might engage in some form of exclusionary conduct in the future, the full weight of Section 2 of the Sherman Act would be available to remedy any such conduct. But the legal test applied to acquisitions is whether there is a basis for predicting that the transaction will make it substantially more likely that the combined firm *will* engage in illegal exclusionary conduct in a defined relevant market. That test seems very unlikely to be met.[23]

In this case, the Commission concedes (as it must) that no market yet exists for the early cancer detection offering that Grail is attempting to develop. Due in part to the extensive requirements for

[23] In fact, the antitrust enforcement possibilities are even more potent than described: under the "time-of-suit doctrine" adopted in *United States v. E. I. du Pont de Nemours & Co.*, 351 U.S. 377 (1956), vertical transactions can be challenged even decades after consummation if the ownership interest is eventually used to restrain competition. Although subject to criticism on a variety of practical and policy grounds, the doctrine has been recognized as recently as the district-court decision that provisionally dismissed the FTC's antitrust complaint against Facebook. *Federal Trade Commission v. Facebook, Inc.*, Civ. Ac. No. 20-3590 (JEB), at 51-52 (D.D.C. June 28, 2021).

regulatory approval, the emergence of any such market—if it does occur—may be years in the future. The FTC asserts no basis for any present conclusion that Illumina is likely to engage in exclusionary conduct if and when such a market does emerge. The Commission's assertion that parties could engage in anticompetitive conduct to exclude possible future competitors from a possible future market, pushes the notion of antitrust "incipiency" past the realm of speculation and into fortune-telling. Any store-front psychic offering similar predictions as if they were valuable market intelligence might be prosecuted for deceptive practices by the FTC.

Acceptance of the Commission's logic as a sufficient basis for prohibiting a garden-variety vertical transaction in these circumstances would amount to a *per se* rule against downstream integration. Given the routine accusation (baseless as it is) by the Neo-Brandeisians that present-day antitrust inappropriately emphasizes short-term price effects to the exclusion of broader concerns such as effects on product quality and innovation, the application of a *per se* rule to downstream integration by a leading innovator to acquire an equally innovative customer would be a shameless contradiction of their own policy premises. If there is any fundamental proposition in modern economics that commands endorsement except at the crack-pot fringes of the profession, it is that innovation is the leading source of economic progress. Innovators constantly wrestle with numerous complex issues in deciding whether to integrate downstream (or upstream) or to license or otherwise arrange for downstream activities related to their creations—development of existing or new applications, production, distribution, marketing, *etc*. A federal antitrust policy of discouraging integration through acquisition could be massively disruptive to basic management processes that we depend upon to assure continuing future innovation and competitive success in numerous economic sectors. Attempts to conduct research and to achieve breakthrough innovation in the detection and treatment of cancer constitute a particularly vital area where the prohibition of common forms of vertical integration (including acquisition), based on a mere possibility of future exclusion that would be challengeable in any event, should be regarded as a dangerous form of antitrust experimentation.

The FTC's conduct in this proceeding represents an extreme shift in recent U.S. antitrust practice. The Commission has exploited a variety of disfavored procedural gambits, even going so far as to magnify its own threat of obstructing a transaction through lengthy administrative litigation with a similarly disfavored procedural trick by the European Commission that will allow the FTC to avoid assessment of its case by the U.S. courts. The FTC is pressing a complaint that seems to be based on a doctrine that integration by vertically related innovators is presumptively illegal, in circumstances where any presumption should run in the other direction. The current Neo-Brandeisian movement—adopting an antipathy to vertical acquisitions based primarily on concerns regarding the leading digital platforms—is now being brought to bear in a distant corner of the biotechnology sector (early cancer detection). The main threat to welfare at issue in this case is not that Illumina will stifle the development of its own breakthrough technology, but that FTC intervention in the "make-buy" decision early in the dynamic innovation process will delay or even extinguish promising efforts to produce a major breakthrough in fighting the second-leading cause of death in the U.S. The first victims of President Biden's Neo-Brandeisians may be the millions of cancer patients of the present and future who could be helped by an NGS-based MCED breakthrough.

