

Four Economic Principles Underlying the FTC's Position Against Reverse Payments in Patent Settlement Agreements

Robert Kneuper

Antitrust challenges to settlements of patent disputes have become the latest focus in the ongoing debate concerning the proper relationship of antitrust law to intellectual property law. In recent years, the Federal Trade Commission and private plaintiffs have brought a series of actions against branded and generic drug manufacturers that settled patent disputes in the context of Hatch-Waxman regulations.¹ In cases, such as *Schering/Upsher-Smith*, *Hoechst/Andrx*, and *Zeneca/Barr*, the FTC and/or private plaintiffs have alleged that patent settlement agreements have caused anticompetitive delays in generic entry costing consumers hundreds of millions of dollars. The FTC has put forth a particularly strong stand against so-called “reverse payment” settlement agreements—agreements involving payments from the plaintiff patent holder to the defendant generic producer.²

Antitrust policy with regard to these types of patent settlements is currently in a state of flux. After a series of initial court decisions in favor of the plaintiffs (mostly in cases involving interim or temporary reverse payments while the patent suit continued), the courts have recently made a number of key rulings supporting the legality of patent settlement agreements with reverse payments. The Eleventh Circuit recently vacated the FTC's order in *Schering-Plough*,³ which the FTC has appealed to the Supreme Court. The Second Circuit ruled against plaintiffs in the *Tamoxifen Citrate Antitrust Litigation* (involving Zeneca and Barr)—a decision that in many ways mirrored the Eleventh Circuit's decision in *Schering-Plough*.⁴ These cases demonstrate a wide discrepancy between the views of the FTC and the courts regarding appropriate antitrust policy in this area—a discrepancy that has far-reaching consumer welfare implications.

■ **Robert Kneuper** is a Senior Economist at Economists, Inc. in Washington, DC. Dr. Kneuper worked previously as an economist at the FTC where he played a major role in developing antitrust policy positions for cases involving patent settlement agreements and was the lead economist on both the *Schering* and *Hoechst/Andrx* cases. The author thanks Peter Greenhalgh, Barry Harris, Henry McFarland, and Bob Stoner for useful comments on this article.

¹ The Hatch-Waxman regulations were implemented to facilitate the approval of generic drugs. Generic drugs are filed with the Food and Drug Administration as an Abbreviated New Drug Application (ANDA). Relevant patent holders are notified of ANDA filings and have up to 45 days to initiate a patent lawsuit even though the generic has not entered the market. After the initiation of the lawsuit, the patent holder is given a 30-month stay during which the generic firm is not permitted to enter the market.

² Such settlements also often include an agreement to delay generic entry until a specific date or until certain conditions are met. I use the term “reverse payment” here consistent with much of the literature discussing this issue. However, this type of patent settlement is different from the more typical situation in which potentially infringing entry has already occurred. In these more typical situations, a settlement usually involves a payment from the defendant entrant to the plaintiff patent holder. Hatch-Waxman settlement agreements, by contrast, occur prior to generic entry and thus prior to a loss of profits by the patent holder. For this reason, the use of the term “reverse payment” (i.e., a payment that is opposite of the expected direction) is probably a misnomer.

³ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (*Schering* appeal). See also *Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (Dec. 8, 2003) (FTC *Schering* decision).

⁴ *Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) (*Zeneca/Barr* appeal).

Economic theory has played a key, and perhaps underappreciated, role in the development of the FTC's position against reverse payments. Indeed, the FTC's opposition to reverse payments can largely be distilled to four basic economic principles. The analysis of each of these principles, and their alleged shortcomings, which follows will demonstrate that, despite the various criticisms of the FTC's position, there remain valid economic reasons for an antitrust policy that strongly discourages settlement agreements with reverse payments.⁵

The Four Economic Principles

Principle #1—The Patent Holder Has Market Power. The first economic principle underlying the FTC's position against reverse payments in patent settlement agreements is the straightforward notion that, because the patent holder would have market power but for the entry of the generic manufacturer, the settlement agreement may be anticompetitive. This market power argument has a simple explanation—economic studies and other evidence generally show that generic entry significantly reduces prices to the benefit of consumers. Thus, a patent settlement agreement that delays generic entry delays this benefit and is anticompetitive.

This market power concern is heightened in situations in which the patent settlement agreement involves the first generic filer, who either is well ahead of others in the patent approval process or can potentially create a bottleneck that will slow entry of later generic competitors. Hatch-Waxman regulations give the first filing generic a period of 180 days of exclusivity that is triggered when the first Abbreviated New Drug Application (ANDA) filer begins marketing its product or when there is a court decision declaring the patent at issue either invalid or not infringed. Thus, an agreement delaying entry of the first generic can potentially delay entry of all other generics.⁶

Principle #2—Economic Incentives Encourage Delayed Generic Entry. The second principle is that the patent holder and the potential generic entrant have strong economic incentives to negotiate a settlement agreement that delays generic entry. The parties' incentives favor delaying entry because the patent holder's profit loss after generic entry is generally much greater than the generic firm's profit gain. This is because generic entry generally leads to significantly lower prices and lower profits available to generic entrants compared to what previously existed for the branded product. Thus, both parties can gain from a delay in generic entry as long as the patent holder compensates the generic firm at or above the level of profits lost due to the delay. Such compensation could take many forms, including a reverse payment.

Thus, a patent settlement agreement in the context of Hatch-Waxman may provide the patent holder and the generic entrant with mutually beneficial gains, assuming the generic entrant is compensated by at least the amount of profits forgone by the delay in generic entry. If not for such compensation, the generic entrant's economic incentive would instead favor pressing ahead with litigation to achieve a judgment against the branded patent holder as quickly as possible.⁷

⁵ I characterize the FTC's position against reverse payments in patent settlement agreements based on my own reading of the decisions of the FTC's Commissioners in this area, as well as the positions taken by FTC staff in their legal filings. However, the views expressed in this article are ultimately my own and do not necessarily reflect the views of the FTC, any individual Commissioner, or Commission staff.

⁶ Later generic entrants can, of course, break any bottleneck by winning their litigation against the patent holder. However, the first filing generic generally has the most to gain financially from a quick settlement of the litigation.

⁷ An exception to this general rule can occur in a high-growth market. If the market is growing faster than the rate of interest, the first filing generic firm entitled to the 180 days of exclusivity may actually benefit from a delay in generic entry even without a reverse payment.

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Principle #3—Patents Are Probabilistic Property Rights. The third economic principle underlying the FTC’s position against reverse payments is that patent rights are properly viewed as probabilistic property rights; that is, there is some probability that the patent will be upheld in court, but this outcome is uncertain. Thus, the financial value of the patent to its holder depends upon both the expected profit stream and the probability that the patent will be upheld.

For some settlement agreements, it may be possible to estimate the probability (or range of probabilities) that the patent holder would have prevailed in the patent suit. The patent holder could, for example, have retained an objective fact finder to review the evidence and estimate the patent holder’s likelihood of prevailing. This probability (or range of probabilities) could then be used to estimate the likely date (or range of dates) of generic entry as a result of litigation. This date (or dates) can then be compared to the date of entry under the settlement agreement to see if the agreement likely delayed generic entry.⁸

However, in practice it is often difficult to measure the patent holder’s probability of winning the patent litigation.⁹ While pleadings and other court documents may be available to antitrust enforcers (or private plaintiffs), other types of evidence may be privileged or otherwise unavailable. Even where sufficient information is available, there are other practical impediments to directly applying this approach.¹⁰ For these reasons, the FTC has generally relied on the fact of the reverse payment as the most accurate barometer of an anticompetitive settlement agreement. This has led in practice to a presumption that reverse payment settlements are anticompetitive, thereby placing the burden upon the defending parties to overcome this presumption by presenting evidence supporting alternative explanations for the reverse payment.¹¹

Principle #4—Aggressive Antitrust Enforcement Benefits Consumers. The fourth economic principle underlying the FTC’s position against reverse payments is that aggressive antitrust enforcement in this area benefits consumers, particularly for settlements involving “blockbuster” drugs. This is because the delay in generic competition to blockbuster drugs would likely cost consumers billions in lost savings from lower-priced drugs, whereas saved litigation expenses associated with a patent settlement for such drugs will amount only to a few million. From this perspective, the financial risk to consumers of under-enforcement is great compared to the financial risk of over-enforcement.

More generally, this idea can be illustrated by imagining two extreme worlds: one in which all Hatch-Waxman-type settlement agreements involving a reverse payment are presumptively legal,

⁸ This approach is consistent with a more general standard proposed by economist Carl Shapiro. Shapiro argues for a standard that balances the rights of the patentees with consumer interests, stating that “consumers have a ‘property right’ to the level of competition that would have prevailed, on average, had the two parties litigated the patent dispute to a resolution in the courts.” See Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 10–11 (2003).

⁹ In some cases, a probabilistic approach can be used even without knowing the likely range of probabilistic outcomes. For example, suppose that the two parties have agreed to a settlement that includes a reverse payment and generic entry at the end of the patent life. In such cases, as long as the generic firm had some chance of winning the patent case, the probabilistic model would predict an entry date under litigation before that in the settlement agreement.

¹⁰ For example, one such complication involves estimating the likely economic life of the patent. If the economic life is shorter than the patent life, the economic life should be used under the probabilistic approach. However, the economic life of the patent can be unclear because of the uncertainty associated with the potential approval and entry of competing drugs. For a discussion of various other practical impediments to this approach, see FTC *Schering* decision, *supra* note 3, at 34–35.

¹¹ In its *Schering* decision, the FTC states: “If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.” FTC *Schering* decision, *supra* note 3, at 26.

versus another in which such settlements are presumptively illegal.¹² In the presumptively legal world, the potential harm to consumers from an antitrust perspective could be measured by totaling the consumer welfare losses associated with anticompetitive settlement agreements. By contrast, in the presumptively illegal world, the potential harm to consumers would derive from settlement agreements that were not reached due to the rule against reverse payments. In the short-term, the parties' litigation expenses could be a reasonable proxy for these losses.¹³

From the FTC's perspective, the presumptively legal world leads to very significant consumer welfare losses because the settling parties have an incentive to negotiate delays in generic entry until the end of the patent life. By contrast, the presumptively illegal world leads to relatively low consumer welfare losses because such losses would likely be limited to the litigation expenses incurred as a result of the inability to reach settlement agreements that did not include a reverse payment provision.¹⁴

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This idea can be illustrated by considering the patent settlements that were the subject of a 2002 FTC study. The study reviewed 104 New Drug Applications resulting in 75 patent lawsuits. The median net sales level of the drugs involved in the 75 lawsuits was \$190 million annually.¹⁵ Assume that a presumptively legal policy existed and that all of the lawsuits settled, resulting in an average delay in generic entry of five years beyond what would have occurred had there been litigation. This outcome would result in consumer welfare losses of approximately \$32 billion or \$6.4 billion for each year of delay associated with the 75 patent lawsuits.¹⁶ By contrast, the savings associated with reduced litigation expenses are \$375 million if litigation expenses of \$5 million per lawsuit are assumed. Thus, the losses from delayed entry are approximately 85 times the size of the litigation savings. From this perspective, an antitrust policy deterring patent settlements with reverse payments promotes consumer welfare.

¹² The appellate decisions in *Schering* and *Zeneca/Barr* are somewhat akin to the presumptively legal world, whereas the FTC's position is somewhat akin to the presumptively illegal world.

¹³ The short- and long-term social costs associated with a strong rule against patent settlement agreements with reverse payments are unclear. In the short term, fully litigated outcomes do provide social benefits that may well exceed litigation costs. Such benefits derive from the fact that the ultimate legality of the patent is resolved and made known not only to the settling parties, but to other firms as well. In the long term, a policy that "chills" settlement agreements could lead to reduced investment in innovation. However, this effect is unclear because patent holders may also be deterred from pursuing investment efforts relating to products likely to have relatively weak patent protection relative to products likely to have relatively strong patent protection. In other words, patent holder investment decisions could potentially be more efficient under an antitrust policy that discourages patent settlement agreements with reverse payments.

¹⁴ A reverse payment is only one of many options that can be used by parties attempting to settle a patent dispute. Other options include changing the generic entry date, providing a payment flowing from the generic firm to the branded firm, side licenses involving other products, other side agreements such as manufacturing, distribution, and marketing agreements, etc. From the FTC's perspective, any side transactions need to be at fair market value, and not a hidden way to make a reverse payment. The FTC's 2002 study of patent settlement agreements demonstrates that a reverse payment is not necessary to reach a patent settlement agreement in a Hatch-Waxman setting. See *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* (July 2002), available at http://www.ftc.gov/os/2002/07/generic_drugstudy.pdf [GENERIC DRUG STUDY]. The study found that 20 of the 53 paragraph IV patent suits involved a resolution that included a settlement and 11 of the 20 settlements did not involve a reverse payment. Under seven of these settlements, the brand firm licensed the generic firm to either enter the market immediately or relatively soon after the settlement agreement. Two other settlements involved supply agreements pursuant to the brand's New Drug Application. While these other types of settlement agreements are not free from potential antitrust concerns, they do demonstrate economically viable settlement options that go beyond the simple use of a reverse payment.

¹⁵ See *id.* at 14.

¹⁶ This calculation assumes that the annual generic share of the market is 90% and that the fall in the price as a result of generic entry is 50%. This means that the consumer welfare gain from generic entry in a \$190 million market is $.9 \times .5 \times 190$ or \$85 million annually (assuming a perfectly inelastic demand curve). This calculation ignores the potential consumer welfare losses from generic entry as discussed in the criticisms of the FTC's position that the patent holder has market power.

Criticisms of the Economic Principles

Principle #1—The Patent Holder Has Market Power. The primary criticism against this principle is that in certain instances the patent holder does not have market power, and that delayed generic entry does not lead to anticompetitive effects because consumers may actually benefit from delays in generic entry (or even no generic entry). Generic entry may not only reduce product prices to the benefit of consumers but also reduce promotional activities to the detriment of consumers. Promotion of pharmaceutical products tends to increase the demand for such products (or can change the shape of the demand curve) and some particular types of promotions, such as sampling, provide direct benefits to consumers. This means that generic entry can in some situations be output reducing and that the consumer welfare losses from reduced promotional activity due to generic entry can partially or fully offset the consumer welfare gains from the fall in price. This argument can be particularly relevant where the availability of an important drug depends heavily on promotions.

A version of this argument was made by one of the defendant's economic experts in the *Schering* case, Sumanth Addanki. Addanki argued that it was incorrect to infer market power simply from the price impact of generic entry.¹⁷ The product at issue in that case was a potassium chloride supplement sold by Schering under the brand name K-Dur 20. Many other potassium chloride supplements were on the market but K-Dur 20 was the only 20 mg size supplement available and the only once-a-day supplement available. As a result of successfully marketing these additional benefits of K-Dur 20 to physicians, Schering garnered a significant share of all potassium chloride sales, as well as a substantial price premium. However, Addanki argued that any price premium on K-Dur 20 was purely the result of Schering's marketing efforts and was not a price premium associated with market power. This view was ultimately rejected by the FTC, which instead focused on two key pieces of evidence: (1) the parties' documents predicting significant consumer welfare benefits from generic entry; and (2) ex-post entry data demonstrating significant average price decreases for the brand and its corresponding generic after generic entry.¹⁸

But the question remains: How does one reconcile the potential consumer welfare losses and gains from generic entry in particular cases? Obviously, a careful consideration of the evidence and underlying data is important. For example, if no significant consumer welfare losses from generic entry are predicted in the parties' generic impact forecasts, this may raise doubts as to the credibility of an argument that such losses are great. An analysis of pricing and marketing data associated with actual generic entry can also be useful. However, translating such measures into estimates of actual consumer welfare losses can be very difficult. Overall, given the numerous studies that have shown the significant consumer welfare benefits from generic entry in general, a reasonable approach may be to presume market power under two conditions: (1) evidence indicates that generic entry provides unique and significant price benefits to consumers; and (2) there is no evidence of a substantial output reduction as a result of generic entry.¹⁹ This would then place the burden upon defendants to overcome the presumption by demonstrating on a case-by-case basis that generic entry will not harm consumers overall.

¹⁷ For a summary of Addanki's arguments, see his slide presentation entitled, "Schering-Plough and the FTC's Unusable 'Direct Test' of Monopoly Power in Pharmaceutical Markets," available at http://www.nera.com/event.asp?e_ID=2498.

¹⁸ See FTC *Schering* decision, *supra* note 3, at 19–23.

¹⁹ The price effect and output effect of generic entry are generally measured using sales of both the branded drug and its generic counterpart.

Principle #2—Economic Incentives Encourage Delayed Generic Entry. The primary criticism of this principle is that the incentive to privately negotiate a delay in generic entry through a settlement agreement may be offset by other factors, including the threat of treble damages from an antitrust suit. In other words, incentives alone are not a sufficient basis to conclude that a “bad” settlement agreement will be negotiated.²⁰ For example, assume that the parties negotiating a settlement with a reverse payment perceived a 50/50 chance of “getting caught” by antitrust authorities. In such a situation, the prospect of potential treble damages may be sufficient to fully deter the parties from negotiating a settlement agreement with a reverse payment.

This is not so much an argument against aggressive antitrust enforcement in this area but an argument against simply assuming that the strong incentives towards delaying generic entry will always lead to settlement agreements that delay generic entry. After all, the incentives to negotiate a delay depend on many factors, including the parties’ perceptions of the likelihood of antitrust enforcement as well as the penalties associated with such enforcement. However, the profit-gain incentives do inform the analysis in that they show a logical profit-maximizing rationale tying reverse payments to delayed generic entry. Indeed, few would doubt that if reverse payments were presumptively legal, the vast majority of settlements would involve generic entry dates at the end of the patent life, or alternative formulations to achieve the same result.

Principle #3—Patents Are Probabilistic Property Rights. While economists have generally embraced the concept of patents as probabilistic property rights, some have disagreed with the FTC’s approach of presuming delay from the fact of a reverse payment.²¹ These economists have put forth alternative explanations for a reverse payment, including risk aversion, asymmetric information, etc. For example, in the *Schering* case, Addanki argued that risk aversion can be used to explain reverse payments. According to Addanki, “the risk averse patentee would be willing to settle for a ‘date certain’ earlier than the expected date under litigation so as to avoid the risk associated with the litigation.”²² Another economic expert, Robert Willig, made similar arguments relating to asymmetric information and liquidity constraints. For example, Willig hypothesized that “a ‘cash starved’ generic may actually be able to enter earlier and more effectively if it receives some up-front support from the pioneer manufacturer.”²³ From this perspective, reverse payments are consistent with no delay in generic entry and contrary to the FTC’s approach of presuming delay from reverse payments.

The appellate courts in the *Schering* and *Tamoxifen* cases appear to have agreed that logical explanations exist for “reverse payments” beyond simply a payment for delay. In *Schering*, the court stated:

²⁰ In its *Schering* decision, the FTC acknowledged that “[t]he existence of these strong incentives standing alone, obviously does not amount to proof of a law violation, but it may help to resolve conflicting inferences.” FTC *Schering* decision, *supra* note 3, at 27.

²¹ The two recent appellate decisions in *Schering* and in *Zeneca/Barr* have bypassed the probabilistic approach in favor of simply presuming the validity of the patent. Such a standard can be interpreted in several ways. One interpretation would be that the plaintiff must first overcome the presumption of a valid patent before it can argue that a settlement agreement with a reverse payment is anticompetitive. This would presumably involve a trial on the merits of the patent in an attempt to show that the patent would likely have been found invalid. A second interpretation would be that courts are simply assuming a 100% likelihood that the patent would have been held to be valid in court. Either of these interpretations would seem to have the effect of making all patent settlements with reverse payments presumptively legal with certain limited exceptions (e.g., situations involving sham litigation).

²² See Sumanth Addanki, *Schering-Plough and the Antitrust Analysis of Patent Settlement Agreements in Pharmaceutical Markets*, ANTITRUST INSIGHTS, (NERA NEWSL.), May 31, 2005, at 5, available at http://www.nera.com/Newsletter.asp?n_ID=31.

²³ FTC *Schering* decision, *supra* note 3, at 38.

Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch-Waxman scheme, ESI and Upsher gained considerable leverage in patent litigation: the exposure to liability amounted to litigation costs, but paled in comparison to the immense volume of generic sales and profits.²⁴

The FTC has not rejected the notion that there are potential alternative explanations for reverse payments. But, in their enforcement actions, the FTC has stated that it has not found sufficient evidence supporting these other explanations to overcome the presumption of delay. Moreover, the FTC expressed skepticism regarding the notion that a reverse payment is a natural byproduct of the Hatch-Waxman setting, stating that “we do not have evidence before us to justify any conclusion that payments by pioneers to generics are a ‘natural by-product of the Hatch-Waxman process.’”²⁵

From an economic perspective, these alternative explanations depend on a specific set of theoretical assumptions concerning the patent holder and the potential generic entrant. For example, from the perspective of standard bargaining theory, an argument tying a reverse payment to risk aversion holds only if the patent holder is in a more risk averse position compared with the generic. The simple fact that the patent holder may be exposed to a greater financial loss from an adverse outcome as compared with the generic does not automatically translate into greater risk aversion. A firm’s level of risk aversion depends on many factors, including the available ways in which particular firms can diversify against adverse outcomes.

Overall, in considering alternative economic explanations for reverse payments it is important to carefully consider the assumptions underlying economic models of firms’ negotiating behavior, as well as the available evidence relating to such assumptions. From the FTC’s perspective, such arguments are all too often made in a theoretical vacuum without careful consideration of the actual facts of the case.

Principle #4—Aggressive Antitrust Enforcement Benefits Consumers. With respect to this issue, there appears to be some concern by some economists and the courts that a rule against reverse payments will have a significant chilling effect on patent settlement agreements. For example, the *Schering* decision quotes from another ruling by Judge Richard Posner, in which he stated that “any settlement agreement can be characterized as involving ‘compensation’ to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus classified as involving a forbidden ‘reverse payment,’ we shall have no more patent settlements.”²⁶

From the FTC’s perspective, this argument certainly raises concerns regarding a rule against any type of compensation from the branded plaintiff to the generic defendant as part of a patent settlement. But the FTC’s rule is not against any type of compensation—it applies only to settlement agreements with reverse payments or side deals and other arrangements that mask a reverse payment (i.e., not fair market-valued transactions). Many patent settlement agreements have not resulted in FTC enforcement actions despite providing some form of compensation to the generic firm. This includes licenses of the generic firm, side licensing deals, supply arrangements, etc. In addition, settlement agreements with relatively small reverse payments (e.g., under \$2 mil-

²⁴ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005).

²⁵ FTC *Schering* decision, *supra* note 3, at 29.

²⁶ See *Schering* appeal 402 F.3d at 1074 (quoting *Asahi Glass Co. v. Pentech Pharm.* 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003)).

lion) are still allowed under the FTC's rule as long as they are reasonably related to litigation expenses.

More generally, even if the FTC's rule against settlement agreements with reverse payments did have a significant chilling effect, this does not necessarily mean that such a policy is unsound. As stated earlier, a valid argument can be made that even if all settlement agreements with reverse payments were presumptively illegal, such a policy would likely be consumer-welfare enhancing. While patent litigation can be expensive, it may be more expensive to allow anticompetitive delays in generic entry.

Conclusion

The FTC's position against reverse payments in patent settlement agreements is an important and controversial area of antitrust enforcement. The merits of the FTC's position have been debated extensively, but primarily from a legal perspective. The focus of this analysis has instead been on the economic principles underlying the FTC's position. These principles demonstrate the existence of strong economic and consumer welfare reasons for the FTC to continue to pursue an antitrust policy that strongly discourages settlement agreements with reverse payments. ●