Generic entry in the pharmaceutical market: why less is better.

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April 2018

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Abstract

This paper models an economy with one incumbent firm producing a patent protected drug and two potential entrants. After patent expiry, the generic producers play a fixed cost entry game in which entry by both is unprofitable due to intense price competition – therefore each enters with a low (high) probability if entry costs are high (low). Early entry agreements allow one generic producer to enter just before patent expiry, thus foreclosing the market for the other generic producer. Surprisingly, we find that under price competition such agreements are always welfare enhancing, even when entry costs are so low that entry by both generics is virtually costless and thus almost certain in the absence of early entry agreements. Consumers are made worse off by early entry agreements if entry costs are sufficiently low, but for intermediate entry costs, the consumer and industry incentives are aligned in favor of early entry.

Keywords: early entry agreements, market foreclosure

JEL classification: L13, L41, I11.

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1 The market of early entry agreements

In pharmaceutical markets, an originator detaining a valid patent benefits from an exclusivity period during which no generic version of the drug can be marketed. Only the expiry of the patent opens the market to generic entry.[1]

A common practice among drug companies is to conclude so called "early entry agreements" by which the originator firm allows for premature entry (before patent expiry) by one generic producer. This behavior has for example been documented by the European Commission's sector enquiry of 2009, that finds that 30% out of all non-litigation agreements are arrangements about the early entry of a generic. Early entry agreements are in fact more common than the very mediatized pay for delay agreements.[2] The timing of early entry is carefully selected by the incumbents; in 80% of the cases, such agreements occur less that a year before patent expiry.[3] In view of this very short time period, early entry agreements may be thought to have no significant effects. Further, as these agreements result in premature generic entry and lower prices, consumers may even be better of. We will show otherwise, that early entry can have lasting competitive and welfare effects.

An example that received media attention occurred in August 2005, when Bristol-Myers Squibb's patent for cholesterol drug *Selipran* expired on the Swiss market. At that time, *Selipran* was a true blockbuster drug on the Swiss market; it was the second most sold drug with a turnover of 68 million Swiss francs. Three months before patent expiry, in June 2005, the generic version of *Selipran*, *Pravalotin*, started being sold on the market by generic producer Mepha. Mepha is said to have paid Bristol-Myers Squibb a seven figure sum for this early entry.[4]

Such behavior raises several questions. Why is a generic producer willing to pay such a high fee to enter the market just three months before patent expiry? If early entry is a means to better price discriminate, then why would such an agreement not take place at an earlier date, or why did the incumbent not market himself a generic version of the drug during the patent period? Did this agreement benefit consumers? What should public policy be with respect to such agreements? In this paper we provide a model that rationalizes this behavior and allows us to answer these questions.

We study an economy where the incumbent firm produces a drug that is initially protected by a patent and where two potential entrants can produce a generic version of the same drug. The incumbent enjoys a first mover advantage such that he perceives higher revenues than the entrants. In accordance with the facts described above, in our model the incumbent has no interest to allow the entry of a generic producer within the patent period to exploit

[1]See section 2.1.8. of the Sector Inquiry (European Commission [9]) In Europe, total patent protection is typically up to 10 years. In the US, patent protection is differentiated from exclusivity protection (U.S. Food & Drug Administration [30] FDA-CDER-SBIA [12]). In this paper I will assume that a valid patent will grant monopoly exclusivity to the originator until the patent is expired, which opens the market for generic entry.

[2]Only 20% out of all patent settlement agreements are concerned with pay for delay (45 deals out of 207 patent settlements). The Commission recorded 87 early entry agreements out of 285 non-litigation agreements for the years 2000-2007. See Sector Inquiry (European Commission [9]).

[3]Paragraph 817 of the Sector Inquiry (European Commission [9]). As some incumbent firm reports: *"[...] we should plan for generics next year but wait before implementation of some activities ie supply agreements, trading deals etc until there is much more evidence that a generic [...] product will be launched."* See paragraph 819 of the Sector Inquiry (European Commission [9]).

[4]See Schlatter [24].

heterogeneity in consumers' valuations. Instead, when it takes place, early entry is only intended to change market entry and competition in the post-patent period.

We will first solve for the general model of entry pre- and post-patent expiry, where the level of entry costs determines the outcome of the game. This general model makes abstraction of any specific form of competition between entrants and incumbent. In a second stage and in order to make welfare and consumer surplus statements, we will apply this model to an economy where goods are vertically differentiated.

In the absence of early entry agreements, once the patent expires, each entrant chooses simultaneously and independently if it wishes to pay a fixed fee and enter the market or stay out. After entry decisions have taken place, all firms in the market compete in prices or quantities. Entry is profitable for a single entrant. However, since intense competition renders entry by both unprofitable, in equilibrium each generic producer enters with a low (high) probability if entry costs are high (low). Thus if entry costs are low a competitive situation with double generic entry is very likely, whereas monopoly by the incumbent is very likely if entry costs are high.

With early entry agreements the generic producers make simultaneous offers to the incumbent to obtain the exclusive right for an early entry, which if accepted renders an entry decision observable to the rival entrant before the patent expires. If the incumbent accepts such an offer then the market becomes foreclosed for the other generic producer.

We use a vertical differentiation model to show that early entry is always welfare enhancing if incumbent and entrants compete in prices, irrespective of the level of entry costs. This is perhaps unexpected since, when entry costs are low, entry by both generics is almost certain yet costless and competition is then maximized. In a vertically differentiated economy the incumbent produces a high quality version of the drug (the brand product), focusing on high valuation consumers, whereas the entrants produce a lower quality generic version of the same drug, targeting lower valuation consumers. We explain this welfare result by showing that the high quality producer tends to respond aggressively to single entry by a low quality competitor (by expanding the fraction of consumers it serves). Instead, entry by multiple low quality competitors pricing at marginal cost is accommodated (by focusing on those consumers that value quality the most and on which it can still get a significant margin). It turns out that the welfare gain from serving a few more consumers the high quality good outweighs the welfare gain from serving all remaining consumers the low quality good. To our knowledge this counterintuitive effect has not been documented in the literature before. If firms compete in quantities, early entry may be welfare enhancing if fixed costs are sufficiently low.

Since early entry agreements result with certainty in an environment with limited competition, consumers are better off in the absence of early entry agreements when entry costs are low (since then intense competition is very likely) and worse off when those costs are high (since instead the incumbent is very likely to remain a monopolist). From the industry perspective the opposite is true. The incumbent is accepting early entry as a means to avoid intense competition if entry costs are low, whereas if entry costs are high, he will be better off in the absence of early entry agreements. It remains that there exists a range of intermediate entry costs such that consumer and industry incentives are aligned in favor of early entry.

The general part of our model is probably most closely related to the work of Rockett (1990). Rockett suggests a model where an incumbent may choose to license a weak or a strong entrant, the former being less profitable. The incumbent now faces a tradeoff between licensing to a weak firm (getting less revenue from the license) and granting entry to a weaker competitor (inducing greater profits for the incumbent after entry). Licensing both the weak and strong entrant is never profitable as this induces excessive entry. This tradeoff is profitable only in industries with moderate entry costs and strong patent protection. The model allows the incumbent to influence the post-patent situation by changing the order of entrants but not by changing the number of entrants. In that sense, Rockett's model is one where entry is already coordinated, whereas our model allows the incumbent to use early entry agreements as a means to coordinate entry, in particular when generic firms use a mixed strategy to enter the market. Additionally, Rockett's analysis is only in reduced form, making statement about consumer surplus and welfare impossible.

We believe that the vertical differentiation model is particularly well suited to illustrate pharmaceutical markets and the competition between branded and generic products. We exploit the perceived quality difference by the consumer between branded and generic drugs. Although from a bioequivalence point of view both drugs are identical, consumers are willing to pay higher prices for the branded version of a drug.[5] Medical studies have shown that patients report significantly better effects when consuming branded versus unbranded products. This brand bias is reinforced when consumers are regular users of the test brand.[6] Waber et al. (2008) show that consumers report greater pain relief for a opioid analgesic when they are informed that the price for the drug is the regular price of \$2.50 per pill rather than the discounted price of \$2.40.[7] Beyond the placebo effect, other minor quality differences may affect the consumption choices, such as size, color or coating of the tablet, differences in the release systems or simply the packaging. Since for most prescription drugs, the consumption choice is made by the physician in accordance with the pharmacist and the healthcare provider rather than by the patient, our analysis is particularly well suited to the market of over the counter drugs. The willingness to pay can be interpreted as the true willingness to pay of the consumers and is not biased by moral hazard.

There is an extensive existing literature on vertical differentiation models, going back to the work by Gabszewicz and Thisse (1979) and Shaked and Sutton (1982). In the absence of entry threat, product differentiation relaxes price competition. Their version of a vertical differentiation model with two firms has been further formalized by Choi and Shin (1992) and Wauthy (1996). Mussa and Rosen (1978) confront price discrimination with quality differentiation by a monopolist and find that consumers with a low taste for quality impose a negative externality on the monopolist's ability to extract consumer

[5]In the EU, the generic enters the market with a price of around 25% lower than the branded version, a price lowering even further to 45% over time. In the US, a generic typically enters with a 20% discount on the branded products, a discount that can lower to 80% in mature and competitive generic markets. See Sector Inquiry of the European Commission [9] and U.S. Food & Drug Administration [30] Statement on Pay-for-Delay.

[6]In a controlled clinical trial where subjects where informed of the brand versus no-brand status of the given preparation (but not whether it contained a placebo), Branthwaite and Cooper [2] find that the reported mean pain relief after taking 325 mg of aspirin was significantly higher with the branded active preparation than with the unbranded active preparation (2.7 versus 2.48 respectively 2.77 versus 2.48 for users of the test brand).

[7]The actual dispensed product to all participants was an inactive preparation. This placebo effect is also observed for non medical products for example in energy drinks, see Shiv et al. [26].

surplus form the high value consumer. As a result, the monopolist generally decreases the quality if compared to the perfectly competitive framework in order to keep a separation between low and high types. These baseline models have been intensively used to model entry deterrence. While Hung and Schmitt (1988) showed that threat of entry may reduce quality differentiation, Donnenfeld and Weber (1992, 1995) concluded that entry can be deterred by competing incumbents if they exploit their product differentiation conditional on fixed costs being sufficiently high. Lutz (1997) demonstrates that the role of costs in a framework where quality choice is used for entry deterrence is crucial. If the cost of production is quality dependent and identical for the entrant and the incumbent, the latter will always deter entry and choose a quality lower than with accommodated entry. In an entry model with vertical differentiation and quality dependent marginal costs of production, Noh and Moschini (2006) find that welfare can be higher if entry is deterred rather than accommodated, depending on the level of fixed entry costs and consumers' taste for quality.

In our work quality is exogenous and we focus instead on what can be better seen as an entry facilitating practice, used by the incumbent to manage competition and extract profits from rivals when there are multiple potential entrants. The setup of our model with the inclusion of a mixed strategy also allows to consider double entry. As Bertrand competition between the entrants conventionally precludes double entry, this is traditionally overlooked. As our work shows, exploring this case can however lead to interesting results.

Anticompetitive conducts in the pharmaceutical sector have been a hot topic in many jurisdictions over the last decade, notably in the US and Europe. Much of the case law focuses on pay for delay deals, where the originator delays entry by generics in order to extend its monopoly period. Pay for delay agreements are used as a means to circumvent frequent and costly litigation about the validity of the patent before its official expiry date. The strength of the patent and the level of litigation costs are therefore crucial components of the models in pay for delay literature. However, instead of delaying generic entry, which will occur sooner or later with certainty, our model is about anticipating and thereby influencing the degree of generic entry.

There is little economic literature on the topic of early entry, although as mentioned earlier, it is a practice that is commonly used by pharmaceutical companies. From a legal perspective, work by Gallasch (2014) suggests a theory of harm for early entry agreements, mainly focusing on how early entry agreements allow the originator to enforce price setting and supply agreements and other anticompetitive clauses. Rather than advancing a formal analysis of incentives of incumbent and generics, the author considers how the topic of early entry agreements could fit in the existing case law and legislation. In contrast, our work proposes an economic approach towards the analysis of early entry agreements.

In their paper, Palikot and Pietola (2017) try to answer the question of why the incumbent settles some generics with a pay for delay agreement, whereas some other generics are settled via a licensing agreement. They find that the incumbent uses premature entry (in form of a licensing agreement) for the sole purpose of delaying entry of others. Litigation is an equilibrium outcome only for patents with intermediate strength, while weak or strong patents are settled through licensing or pay for delay. Multiple entry allows to model for the externality that is created by a settlement onto the remaining potential entrants. The more entrants are settled, the higher the litigation threat from remaining entrants, as expected profits from successful litigation are increasing. Rather than focusing on the pro- and anticompetitive effects of such agreements, Bokhari, Mariuzzo and Polanski (2017) ask

the question of when pay to delay deals are to be seen in equilibrium. They find that the incumbent, after having paid off a first generic challenger with a pay to delay deal, can use the threat of launching an authorized generic via that first paid-off challenger (using a license) to threaten the second challenger and deter it to seek entry before patent expiry. This threat becomes credible if the first mover advantage to the generic is large enough.

The paper is organized as follows. *Sections 2 and 3* solve the general reduced form model, *section 4* then applies this result to some specific form of competition (Bertrand and Cournot), in order to draw welfare and consumer surplus conclusions. *Section 5* discusses the results and *section 6* concludes. All proofs can be found in the appendix.

2 The model

There is one incumbent I and two potential entrants $i = 1, 2$. The goods of the incumbent and the entrants are differentiated such that at the same prices, consumers weakly prefer to buy the incumbent good. As we will see later, the product differentiation can take the form of a vertical quality differentiation or be derived from a model with loyal and captive consumers.

Marginal costs of all three firms are zero. An entrant needs to pay $F > 0$ in order to enter the market. These fixed costs not only capture technological setup costs but also, for example, the cost the generic firms need to incur when establishing the necessary bioequivalence of the generic drug with respect to the original drug or marketing costs.

The game is an infinite period model, each period containing two stages. The first period, *period 0*, is the early entry agreement period and occurs before patent expiry. In stage one of period 0, an early entrant makes a take it or leave it offer X_i to the incumbent. In stage two, the incumbent decides whether to accept or reject X_i with $a_i = 1$ denoting an acceptance and $a_i = 0$ denoting a rejection. The incumbent can accept at most one offer, thus $a_i a_j = 0$ with $i \neq j$.

The second period, *period 1*, contains an entry stage and a strategic choice stage. In stage one, the entry after patent expiry, a firm i whose offer has not been accepted decides whether to enter or not. Entry by firm i is denoted by $b_i = 1$ and no entry by $b_i = 0$. (For completeness, $b_i = 0$ if $a_i = 1$.) At the end of stage one, the market can either be in an incumbent monopoly m, in duopoly d of incumbent and one entrant or competition c of incumbent and two entrants. In stage two, entrants and incumbent choose their strategic variable x_i respectively x_I, price (p_i, p_I) or quantity (q_i, q_I).

Period 1 is repeated infinitely until at least one firm i enters the market. Firms discount the future at a rate $\delta = e^{-r\Delta}$ with $\delta \in (0, 1)$ and where r represents the interest rate and Δ the time length between the repetitions. Time is denoted by t. The revenue function is given $R_i = \sum_{t=0}^{\infty} e^{-r\Delta t} \int_t^{t+\Delta} p_i q_i e^{-rs} ds$ for firm i and $R_I = \sum_{t=0}^{\infty} e^{-r\Delta t} \int_t^{t+\Delta} p_I q_I e^{-rs} ds$ for the incumbent. We assume that competition decreases revenues both for the incumbent and the entrants such that $R_I^m > R_I^d > R_I^c \geq 0$ and $R_i^d > R_i^c \geq 0 = R_i^m$.

In order for entry by at least one entrant to be profitable, single entry revenue minus fixed costs must be positive. Thus

Assumption 1. $R_i^d - F \geq 0$.

To avoid the trivial case of double entry where early entry will always be accepted by the incumbent, we assume

Assumption 2. $R_i^c - F < 0$.

These assumptions determine the feasible combinations of F that support entry and avoid excessive entry such that $R_i^c = \underline{F}(s_L) < F \leq \overline{F}(s_L) = R_i^d$.

Monopoly is not an absorbing state, meaning that it cannot be sustained in the long run. If no firm enters the market in the entry stage, firms will note that the market can still be explored as $R_i^d - F \geq 0$. If the firms are given a chance to play the same entry game multiple times, eventually one (or two by mistake) will enter the market. As soon as one (or two) firms have entered, the entry game cannot be replayed since $R_i^c - F < 0$. If at least one firm i has entered, only the second stage, the strategy choice stage, is repeated infinitely.

A pure strategy of firm i is $S_i = (X_i, b_i, x_i)$ and of the incumbent $S_I = (a_1, a_2, x_I)$. The corresponding payoffs are

$$\Pi_i = (a_i + b_i)[R_i - F] - X_i a_i$$

$$\Pi_I = R_I + \sum_{i=1}^{2} X_i a_i$$

We are looking for a Markov perfect equilibrium in this dynamic complete information game. This implies stationarity such that the players' strategies depend on the current state only and are not influenced by the strategies of the previous periods.[8] For instructive purposes, we are first solving the game as a one-shot game, where the time length between periods tends to infinity i.e. $\Delta \to \infty$. A general solution to the repeated game is given in *section 3.3.*

3 Strategic behavior

3.1 Behavior after patent expiry

We start by solving the last stage of period 1, the strategic choice stage, in which the entrant(s) and the incumbent compete in prices or quantities.

If no firm i enters the market such that $\sum_{i=1}^{2}(a_i + b_i) = 0$, the incumbent remains a monopolist after patent expiry. Revenues of incumbent and entrants are equal to R_I^m and $R_i^m = 0$. If some firm i but not j enters the market, i.e. $\sum_{i=1}^{2}(a_i + b_i) = 1$, either through early entry in period 0 or through post-patent market entry in period 1, the incumbent competes with firm i in a duopoly. Revenues of incumbent and entrant are equal to R_I^d and R_i^d. If two firms enter after patent expiry, i.e. $\sum_{i=1}^{2}(a_i + b_i) = 2$, the market is in competition. Revenues of incumbent and entrants are equal to R_I^c and R_i^c.

In stage one of period 1, the entry stage, conditional on no firm having entered so far, i.e., if $a_i = 0$ for $i = 1, 2$, the firms play a standard entry game, where each firm i chooses $b_i = 1$ with probability $z_i \in [0, 1]$. If firm j entered ($b_j = 1$), the dominant strategy of firm i is to not enter ($b_i = 0$) as $R_i^c - F < 0$. If firm j did not enter ($b_j = 0$), the dominant strategy of firm i is to enter ($b_i = 1$) as $R_i^d - F \geq 0$.

This subgame has two asymmetric pure strategy equilibria, with firm i entering and firm j staying out such that $b_i = 1$ and $b_j = 0$. These pure strategy equilibria result in a payoff of $R_i^d - F$ for the entrant i, and zero for the non-entrant j.

[8] See Fudenberg and Tirole [13].

This subgame also has a unique symmetric equilibrium, with each firm i entering with a non-degenerate probability $z_i = \frac{R_i^d - F}{R_i^d - R_i^c}$, resulting in zero profit for both firms.

An asymmetric equilibrium requires the firms to coordinate on entry, whereas the mixed strategy equilibrium does not. There is no reason to believe that generic companies coordinate during the application procedure onto the market. In light of the high first mover advantages, we expect generic companies to engage in a race to be the first applicant. Entry decisions are then purely based on the level of fixed costs, which are assumed to be symmetrical in our model.

The most common form to apply for a market authorization in the European Union is through the centralized procedure.[9] Applicants need to file their documents with the European Medicines Agency (EMA), where a scientific committee carries out a scientific evaluation of the request and drafts a report within 210 days. In a second phase, the European Commission with the aid of Member Sates assesses the EMA's recommendation and takes a final decision on the marketing authorization. This second phase is much shorter (37 days) and mostly the Commission follows the EMA's recommendation.

Applications remain confidential until the point where the EMA emits its recommendation to the Commission. This opinion and later the full report are published once the recommendation is forwarded to the Commission. Under the current 8+2 patent system, a generic company can start filing an application after the 8 years of data exclusivity. If the authorization is granted, the drug can be commercialized after 2 additional years, once the marketing exclusivity expires.[10]

These institutional features suggest that the mixed strategy equilibrium is much more likely to be played, and we shall thus focus our analysis on the unique symmetric equilibrium.

Since most games have a least some slight amount of uncertainty, Fudenberg and Tirole (1991) argue that the distinction between pure and mixed strategy equilibria may be an artificial one. In our model, uncertainties may stem from uncertainties in rival's revenues or fixed costs.

Harsanyi (1973) shows that a mixed strategy equilibrium may "almost always" be obtained by taking the limit of a pure strategy equilibrium in a "disturbed" game when these disturbances go to zero. A game is disturbed when the players are uncertain about the rival's payoff due to some small fluctuations in the payoff. The fluctuations in payoffs will mechanically compel the players to approximatively use their pure strategies with the probabilities assigned to them by the mixed strategy, without any deliberate effort. This confirms the stability of any mixed strategy equilibrium.

Early entry agreements have an effect on the competitive outcome after patent expiry depending on whether firms play the pure or mixed strategy equilibrium in the entry game. There is no competition effect if firms play in pure strategy. The early entry agreement represents a pure rent extraction from the entrant by the incumbent and has no consequences on consumer surplus and welfare. If firms play the mixed strategy equilibrium, early entry agreements enforce single generic entry rather than an uncertain outcome. Consumer

[9] This procedure is compulsory for "products derived from biotechnology, for orphan medicinal products and for medicinal products for human use which contain an active substance authorized in the Community after 20 May 2004 [...] and which are intended for the treatment of AIDS, cancer, neurodegenerative disorders or diabetes." See https://ec.europa.eu/health/authorisation-procedures_en
Alternatively, applications can be made via the mutual recognition procedure if there exists already a national marketing authorization or through a decentralized procedure where one member state acts as the reference country.

[10] See p. 127 of the EC report.

surplus and welfare are affected by early entry. Thus, [11]

Lemma 1. *(i) If firms i are playing in mixed strategy, then:*

(a) if there was no early entry, i.e., $a_i = 0$, then each firm $i = 1,2$ enters with probability $z_i = z^* = \frac{R_i^d - F}{R_i^d - R_i^c}$ with $z_i \in (0,1)$. Expected equilibrium profits are

$$\mathbb{E}[\Pi_i] = 0$$
$$\mathbb{E}[\Pi_I] = z^{*2}\Pi_I^c + 2z^*(1-z^*)\Pi_I^d + (1-z^*)^2\Pi_I^m$$

(b) if firm j entered early, i.e., $a_j = 1$, then firm i will not enter and $b_i = 0$. Equilibrium profits are

$$\Pi_j^d = R_i^d - F - X_i, \;\; \Pi_i^d = 0$$
$$\Pi_I^d = R_I^d + X_i$$

(ii) If firms i are playing in pure strategy, then:

(a) if there was no early entry, i.e., $a_i = 0$, then firm $i \neq j$ enters and $b_i = 1, b_j = 0$. Equilibrium profits are

$$\Pi_i^d = R_i^d - F, \;\; \Pi_j^d = 0$$
$$\Pi_I^d = R_I^d$$

(b) if firm j entered early, i.e., $a_j = 1$, then firm i will not enter and $b_i = 0$. Equilibrium profits are

$$\Pi_j^d = R_i^d - F - X_i, \;\; \Pi_i^d = 0$$
$$\Pi_I^d = R_I^d + X_i$$

3.2 Early entry agreement

In the first stage of period one, the offer stage, each entrant makes a take it or leave it offer to the incumbent to obtain an early entry onto the market. Since entrants are symmetric, the incumbent always chooses the highest of the two offers. The incumbent can however also reject both offers and will do so if they are not sufficiently high and $a_1 = a_2 = 0$. If the incumbent and generic firm enter into an agreement, provided that $\underline{F}(s_L) < F < \overline{F}(s_L)$, the incumbent knows for sure that the outcome will be one with single generic competition. If the entrants are playing a mixed strategy, the incumbent has to be at least as well off with the duopoly outcome than with the uncertain outcome. The critical value $\overline{X}$ is such that

$$R_I^d + \overline{X} = \mathbb{E}[\Pi_I].$$

If the entrants are playing a pure strategy, the incumbent uses early entry solely as a means of rent extraction from the entrant. Since the incumbent makes revenue R_I^d with or without early entry, he will accept any offer amount $X_i \geq 0$.

[11] This lemma holds for $\underline{F}(s_L) < F \leq \overline{F}(s_L)$. If $F > \overline{F}(s_L)$, no firm enters in the entry stage, i.e., $b_i = 0$ for $i = 1,2$. Equilibrium profits would be $\Pi_i^m = 0$ and $\Pi_I^m = R_I^m$. If $F \leq \underline{F}(s_L)$, both firms would like to enter in the entry stage and there is no mixed strategy equlibrium. In order to avoid this the incumbent will accept the entry offer $X_i = R_i^d - F$ such that $a_i = 1$, $b_j = 0$. However, both these levels of entry costs are ruled out by *assumption 1* and *assumption 2*.

Definition 1. $\overline{X}$ *is the threshold offer value inducing acceptance, i.e.,* $a_1 + a_2 = 1$ *if* $\max\{X_1, X_2\} \geq \overline{X}$.

If entering firms play a mixed strategy equilibrium, firm i is indifferent between entering before or after patent expiry if

$$R_i^d - F - X_i = \mathbb{E}[\Pi_i].$$

If firms are playing a pure strategy equilibrium, there is no difference in the revenue with or without early entry agreements. In that case, the only interest for an early entry is the certainty of being the chosen firm for entry.

As both firms have the same cost structure, they play a Bertrand-like offer game, resulting in offers that equal their revenue minus fixed costs (provided they expect their offers to be accepted). Thus, if the firms' profit is high enough, i.e., if fixed costs are low enough, they will offer the totality of their profit, such that if $R_i^d - F \geq \overline{X}$, then $X_i = R_i^d - F$ for $i = 1, 2$. If the firms' profit is too low to compensate the incumbent for sure competition, i.e., fixed costs are too high, then $X_i < \overline{X}$. This critical level of the offer is determined by the fixed costs, such that $F^*(s_L)$ solves $\mathbb{E}[\Pi_I] = R_I^d + R_i^d - F$.

Proposition 1. *The outcome of the game is:*

(i) if $\underline{F}(s_L) < F < \overline{F}(s_L)$ *and if the entrants are playing the asymmetric pure strategy entry game such that* $b_i = 1$ *and* $b_j = 0$*, then* $a_i = 1$ *and* $a_j = 0$*. The incumbent always accepts the early entry offer* $X_i = R_i^d - F$ *and uses early entry agreements as a means of rent extraction. Welfare and consumer surplus are not affected by early entry.*

(ii) if $\underline{F}(s_L) < F < F^*(s_L) < \overline{F}(s_L)$ *and if the entrants are playing a symmetric mixed strategy entry game, then the early entry offer* $X_i = R_i^d - F$ *is accepted and* $a_i = 1$ *for some* $i = 1, 2$ *and* $b_j = 0$ *for* $j \neq i$*. The incumbent extracts the rent and early entry has consumer surplus and welfare effects.*

(iii) if $\underline{F}(s_L) < F^*(s_L) < F < \overline{F}(s_L)$ *and if the entrants are playing a symmetric mixed strategy entry game, then* $X_i < \overline{X}$ *and* $a_i = 0$ *and* $b_i = 1$ *with probability* z^* *for* $i = 1, 2$.

From now onwards, according to the reasons discussed earlier, we will assume that entering firms play a mixed strategy game.

3.3 The dynamic entry game

Period 1, consisting of an entry stage and a strategy choice (price or quantity) stage is repeated infinitely. If $b_i = 1$ at some point, only stage two of period 1 is repeated (price or quantity setting). We assume perfect monitoring, i.e., firms can perfectly observe actions taken in earlier periods before simultaneously deciding on the action of the current period. Formally, we define $b^t = (b_i^t, b_j^t)$ as the actions played by firms i and j in period t, representing the action space. The resulting state space $\sigma_{1,2} = \{m, d, c\}$ is composed of monopoly m (if $b^t = (0, 0)$), duopoly d (if $b^t = (0, 1)$ or $b^t = (1, 0)$) and competition c (if $b^t = (1, 1)$). The action space of prices or quantities is irrelevant as they are merely a direct consequence of b^t. Also firms only need to know the outcome of the immediately preceding period i.e. b^{t-1}, resulting in a stationary Markov perfect equilibrium. The actions of the

firms in mixed strategies do not change when moving from the one-shot game to a repeated game. As Elberfeld and Wolfstetter (1999) have shown, the equilibrium probability of entry z_i in the repeated game is the same probability than the one-shot case probability. This gives rise to a transition matrix recording the probability $\zeta_{\sigma_1,\sigma_2}$ of moving from state σ_1 to σ_2.

$$\begin{aligned}\zeta_{\mathrm{m,m}} &= (1-z_i)^2\\ \zeta_{\mathrm{m,d}} &= 2z_i(1-z_i)\\ \zeta_{\mathrm{m,c}} &= z_i^2\end{aligned}$$

with $z_i = z^* = \frac{R_i^d - F}{R_i^d - R_i^c}$.

If $\Delta \to 0$, the entry game is played repeatedly, virtually without any delay. If $\Delta \to \infty$, the time between periods is infinite and the firms play the entry game only once at patent expiry; this represents the one-shot case. The incumbent's expected profit now becomes:

Let $J = z^{*2}\Pi_I^c + 2z^*(1-z^*)\Pi_I^d + (1-z^*)^2 \int_0^\Delta p_I^m q_I^m e^{-rt} dt$

$$\begin{aligned}\mathbb{E}[\Pi_I(\Delta)] &= J + (1-z^*)^2 e^{-r\Delta}\left[J + (1-z^*)^2 e^{-r\Delta}(\cdots)\right]\\ &= \frac{J}{[1-(1-z^*)^2 e^{-r\Delta}]}\end{aligned}$$

As $\Delta \to \infty$, the result is identical to the one-shot case.

$$\mathbb{E}[\Pi_I(\Delta)] = z^{*2}\Pi_I^c + 2z^*(1-z^*)\Pi_I^d + (1-z^*)^2\Pi_I^m$$

As $\Delta \to 0$, we quickly converge to a weighted average of the absorbing states.

$$\mathbb{E}[\Pi_I(\Delta)] = \frac{z^{*2}\Pi_I^c}{z^{*2} + 2z^*(1-z^*)} + \frac{2z^*(1-z^*)\Pi_I^d}{z^{*2} + 2z^*(1-z^*)}$$

Hence, if the entry game is played at a virtually simultaneous pace, we quickly converge to the absorbing states of single and double entry.

4 Consumer and welfare results

4.1 A model of vertical differentiation

In order to compute consumer surplus and welfare levels, we must specify some form of competition and consumer preferences. It can be observed that generic drugs enter the market at a price level considerably lower than branded products, a price differential that persists even after patent expiry. A model particularly well suited to this price gap is a model of vertical quality differentiation. The incumbent produces the product with a high quality s_I, normalized to 1, and each entrant i produces the same good but with a lower quality $s_L \in (0,1)$. While, from a bioequivalence point of view, branded and generic drugs can be perfect substitutes, the disparity in qualities can also reflect consumer loyalty to the incumbent's product, switching costs or regulatory frictions such as different reimbursement

schemes for generic and originator drugs. As cited in the introduction, there is also empirical evidence that drug users report greater effects with branded products.

Consumer preferences are given by

$$U = \theta s - p$$

where s is the quality, θ is the taste for quality, uniformly distributed between $\underline{\theta} = 0$ and $\bar{\theta} = 1$ and p is the non-negative price.[12]

4.2 Price competition

Let θ^*, θ^{**} and θ^{***} solve $\theta^* s_L - \min\{p_1, p_2\} = 0$ (indifferent between buying the generic or not buying at all), $\theta^{**} s_L - \min\{p_1, p_2\} = \theta^{**} s_I - p_I$ (indifferent between buying the generic and buying from the incumbent) and $\theta^{***} s_I - p_I = 0$ (indifferent between buying from the incumbent or not buying at all). If a firm i did not enter the market, we assume for notational convenience its price to be set at $p_i = \infty$. Following the consumer preferences we get following demand functions

$$D_I(p_I, p_1, p_2) = \begin{cases} \bar{\theta} - \theta^{**} = 1 - \frac{p_I - p_i}{s_I - s_L} & \text{if } p_I > \frac{p_i}{s_L} = \min\{p_1, p_2\} \\ \bar{\theta} - \theta^{***} = 1 - \frac{p_I}{s_I} & \text{if } p_I \leq \frac{p_i}{s_L} \end{cases}$$

and

$$D_i(p_I, p_i, p_j) = \begin{cases} \theta^{**} - \theta^* = \frac{p_I - p_i}{s_I - s_L} - \frac{p_i}{s_L} & \text{if } p_i < p_j \text{ and } \frac{p_i}{s_L} < p_I \\ \frac{1}{2}\left(\theta^{**} - \theta^*\right) = \frac{1}{2}\left(\frac{p_I - p_i}{s_I - s_L} - \frac{p_i}{s_L}\right) & \text{if } p_i = p_j \text{ and } \frac{p_i}{s_L} < p_I \\ 0 & \text{if } p_i > p_j \text{ or } \frac{p_i}{s_L} \geq p_I \end{cases}$$

Monopoly: In a monopoly market, the incumbent remains sole producer of the drug even after patent expiry. This solution is straightforward. The monopolist's demand is

$$D_I(p_I, s_I) = \bar{\theta} - \frac{p_I}{s_I}$$

Maximizing the revenue function with respect to price, we get price and revenue

$$p_I^m = \frac{1}{2} \text{ and } R_I^m = \frac{1}{4r}$$

The consumer surplus and welfare become

$$CS^m = \int_0^\infty \int_{\theta^{***}=\frac{1}{2}}^{\bar{\theta}=1} \theta s_I - p_I^m d\theta = \frac{1}{8r} \text{ and } W^m = \frac{3}{8r}$$

where $\theta^{***} = \frac{p_I}{s_I} = \frac{1}{2}$, the threshold below which consumers do not buy any good.[13]

[12] Since $\underline{\theta} = 0$, this means that potentially not all consumers will be served by either the incumbent or the generic. For a complete solution of covered, uncovered and preempted market see Wauthy [32].

[13] Remember that we are accounting revenue streams infinitively such that $R = \int_0^\infty pqe^{-rt}dt = \frac{pq}{r}$. Consumer surplus and welfare functions are also expressed as an infinite stream. To obtain the per period functions, we simply need to multiply the expressions by r.

Duopoly: In a market with one entrant, maximizing the revenue functions $R_I = D_I p_I$ and $R_i = D_i p_i$ with respect to prices, we get the following prices and revenues

$$p_i^d = \frac{s_L(1-s_L)}{4-s_L},\ \ p_I^d = \frac{2(1-s_L)}{4-s_L},\ \ R_i^d = \frac{s_L(1-s_L)}{r(4-s_L)^2} \text{ and } R_I^d = \frac{4(1-s_L)}{r(4-s_L)^2}$$

The demand functions then become

$$D_i^d = \frac{1}{4-s_L} \text{ and } D_I^d = \frac{2}{4-s_L}$$

The incumbent captures twice the entrant's share of the market, and both demands are increasing in s_L.[14]
The consumer surplus is defined as

$$CS^d = \int_0^\infty \int_{\theta^*}^{\theta^{**}} \theta s_L - p_i^d d\theta + \int_{\theta^{**}}^{\bar{\theta}=1} \theta s_I - p_I^d d\theta = \frac{5s_L+4}{2r(4-s_L)^2}$$

where $\theta^* = \frac{p_i}{s_L}$ and $\theta^{**} = \frac{p_I - p_i}{s_I - s_L}$.
Welfare is defined as the sum of profits of both incumbent and entrant and the consumer surplus.

$$W^d = \frac{12 - s_L - 2s_L^2}{2r(4-s_L)^2} - F$$

Competition: Since both entering firms i are symmetric, they set their prices equal to marginal costs, assumed to be zero. Plugging this into the revenue function $D_I p_I$ and maximizing with with respect to the price, we get the following prices and revenues

$$p_i^c = 0,\ \ p_I^c = \frac{1}{2}(1-s_L),\ \ R_i^c = 0 \text{ and } R_I^c = \frac{1}{4r}(1-s_L)$$

The corresponding consumer surplus and welfare become

$$CS^c = \int_0^\infty \int_{\theta^*=0}^{\theta^{**}=\frac{1}{2}} \theta s_L - p_i^c d\theta + \int_{\theta^{**}=\frac{1}{2}}^{\bar{\theta}=1} \theta s_I - p_I^c d\theta = \frac{1}{8r}(1+3s_L) \text{ and } W^c = \frac{1}{8r}(s_L+3) - 2F$$

where $\theta^* = 0$ and $\theta^{**} = \frac{p_I - p_i}{s_I - s_L} = \frac{1}{2}$.

4.2.1 Welfare results

In order to evaluate the effects of early entry, we must compare the equilibrium with and without early entry. We are now assuming that entering firms i are playing a symmetric mixed strategy entry game, such that we are essentially comparing case (ii) and (iii) of *Proposition 1*, i.e. W^d and $\mathbb{E}[W] = z^{*2}W^c + 2z^*(1-z^*)W^d + (1-z^*)^2 W^m$. If the firm i's offer X_i is sufficiently high such that the incumbent accepts the early entry offer, the early entry agreement will result in an immediate entry of firm i (before patent expiry), foreclosing entry by firm j once the patent expires (case (ii)). In the offer X_i is too low, and

[14] Note that these results replicate the general results as presented in section 2.1.1. in Tirole [28] and extensions by Wauthy [32] and Choi and Shin [3].

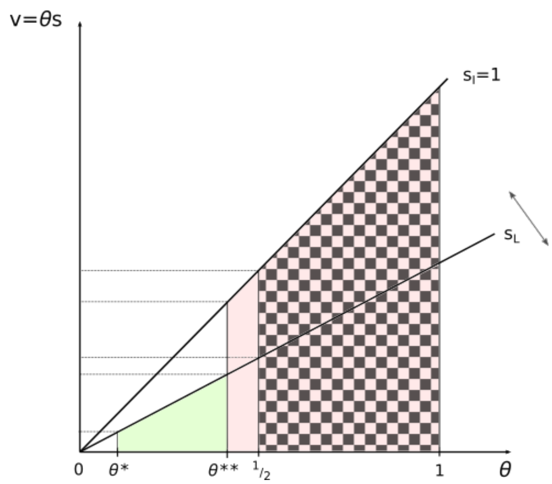
the incumbent refuses early entry, each firm i will enter with probability z^* upon patent expiry (case (iii)).

Against the conventional wisdom that more competition is always welfare improving, we will show that from a welfare perspective, certain early entry by a single firm is always preferred over the equilibrium with probabilistic entry. This result holds irrespective of the level of fixed entry costs. To demonstrate this, we will successively compare the single entry outcome to the no entry outcome and double entry outcome. We will find that welfare in single entry is always highest and we can conclude that a regime with early entry is welfare improving.

Proposition 2. *In terms of welfare, allowing for early entry agreements is always preferred to banning early entry agreements.*

The proof is of interest and therefore discussed in detail along with its intuition in the text below. We will first compare the welfare in duopoly to the welfare in the monopoly scenario. $W^d > W^m$ is satisfied for all $s_L \in (0, 1)$ and for all $F > 0$, i.e. all F within the feasibility frontier. *Figure 1* shows the intuition behind this result and illustrates the expansion effect.

Figure 1: Expansion effect



In the monopoly situation, the covered part of the market is fixed at $\frac{1}{2}$. Only consumers with $\theta \in (\frac{1}{2}, 1)$ will buy from the sole producer on the market, the incumbent. Upon entry of the generic onto the market, increased price competition drives the incumbent's price down. The latter now serves more consumers, the demand increases from $\frac{1}{2}$ to $(1 - \theta^{**})$. The entrant serves the low value consumers, those with $\theta \in (\theta^*, \theta^{**})$. The economic value created by demand expansion represents a total gain in economic welfare. This increase in welfare cannot be offset by the entry costs that entering firm i bears, since by construction firm i only enters if $R_i^d - F \geq 0$ (*Assumption 1*).

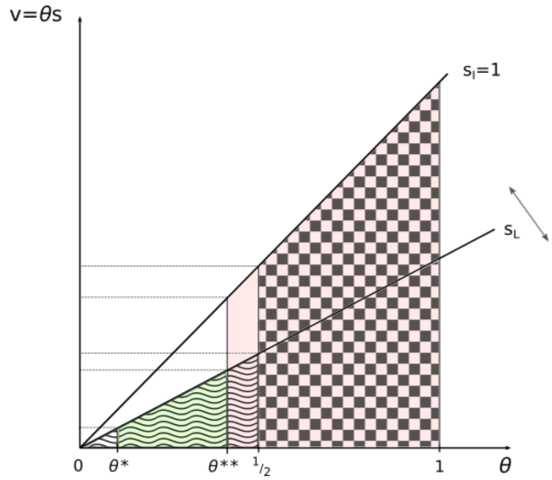
As we move to even more entry, price competition becomes even more intense. We could expect welfare to increase once again. Surprisingly this is not the case, welfare is highest with only one entrant.

$W^d > W^c$ is always satisfied for all $s_L \in (0, 1)$ and for all $F > 0$.

The result that welfare under single entry is higher than welfare under double entry, despite the fact that $p_I^d > p_I^c$ and even for very low fixed costs, can be explained by a

so-called accommodation effect, illustrated in *Figure 2*.

Figure 2: Accommodation effect



Upon entry of the second firm i onto the market, price competition becomes so intense (both firms i price at zero), that the incumbent goes back to its niche strategy of focusing on the high value consumers only. The incumbent now serves again only the upper half of the market, while the generics share the lower half of the market. The welfare loss incurred by not serving the middle value consumers (the ones between θ^{**} and $\frac{1}{2}$) the high quality good is higher than the welfare gain stemming from serving the very low value consumers (between 0 and θ^{*}). Thus, by introducing more competition onto the market, more consumers switch to the low quality good, from which less economic value can be created. Hence, even with lower prices and more consumers being served, welfare is decreasing with more competition. The accommodation effect starts to kick in once $s_L > 0$, where $\theta^{**} < \frac{1}{2}$. The lower s_L, the larger the accommodation effect. Indeed, the lower s_L, the higher the incumbent's profit with single entry, thus the more likely it is becomes that the welfare loss in the θ^{**} to $\frac{1}{2}$ part overrides the welfare gain in the 0 to θ^{*} part.

Again, this result holds independent of the level of fixed entry costs F, since with double entry fixed costs are incurred twice as much as with single entry.

In sum, we can say that as we move from no entry to single entry, the incumbent becomes more aggressive. While the demand is fixed at $\frac{1}{2}$ in the monopoly situation, the expansion effect now allows the incumbent to reach a demand between $\frac{1}{2}$ and $\frac{2}{3}$. As we move from single entry to double entry, the incumbent becomes less aggressive again as his demand falls back to $\frac{1}{2}$.[15]

Since we have just proven that $W^d > W^m$ and $W^d > W^c$, we do not need to know the exact entry probabilities to show that $W^d > \mathbb{E}[W]$. Early entry agreements that enforce the duopoly situation are thus always welfare enhancing.

[15]The demands must however be differentiated from the incumbent's market share that is decreasing as we move from no entry (market share of 100%) to single entry (market share of $\frac{2}{3}$) and to double entry (market share of 50%).

4.2.2 Industry and consumers' incentives

Entering firms i always prefer an early entry since $\Pi_i^d \geq \mathbb{E}[\Pi_i] = 0$. The incumbent prefers an early entry when $\Pi_I^d \geq \mathbb{E}[\Pi_I] = z^{*2}\Pi_I^c + 2z^*(1-z^*)\Pi_I^d + (1-z^*)^2\Pi_I^m$. We know that $\Pi_I^m \geq \Pi_I^d \geq \Pi_I^c$, the higher the prices the higher industry profits. When the probability of double entry z^* is high, which is the case when fixed entry costs F are low, the mixed strategy outcome $\mathbb{E}[\Pi_I]$ will likely be lower than the early entry outcome Π_I^d. Said otherwise, if entry costs are low such that the threat of double entry is high, the incumbent is willing to accept sure competition from a single entrant in order to avoid possible competition from multiple entrants.

The opposite is true for consumers. Consumers value low prices resulting in high consumer surplus, and $CS^c > CS^d > CS^m$. Thus if fixed entry costs are low, consumers value probabilistic entry, as it is likely to result in more entry.

Nevertheless, we find that there exists an area of fixed costs, where both incentives coincide. This area is determined by critical values of fixed costs $F^*(s_L)$ and $F^{**}(s_L)$ such that $\underline{F}(s_L) < F^{**}(s_L) < F^*(s_L) < \overline{F}(s_L)$. $F^*(s_L)$ solves $\mathbb{E}[\Pi_I] = R_I^d + R_i^d - F$, i.e. the values for which the incumbent is indifferent between early entry and the mixed strategy. $F^{**}(s_L)$ solves $\mathbb{E}[CS] = CS^d$, i.e. the values for which the consumers are indifferent between early entry and the mixed strategy.

As the entry game is repeated and as Δ is sufficiently small, the incentives alignement in favor of early entry disappears. As the outcome of a monopoly disappears, the consumers will always be in favor of the mixed strategy providing for more entry whereas the industry will always prefer early entry giving the highest profits.

Proposition 3. *For any level of the entrant's quality $s_L \in (0,1)$, there are critical values of fixed costs $F^*(s_L)$ and $F^{**}(s_L)$ where $\underline{F}(s_L) < F^{**}(s_L) < F^*(s_L) < \overline{F}(s_L)$, such that:*

(i) if $F^{**}(s_L) < F < F^*(s_L)$ incentives of consumers and industry are aligned in favor of early entry.

(ii) if $F > F^*(s_L)$ consumers prefer early entry whereas the industry prefers no early entry.

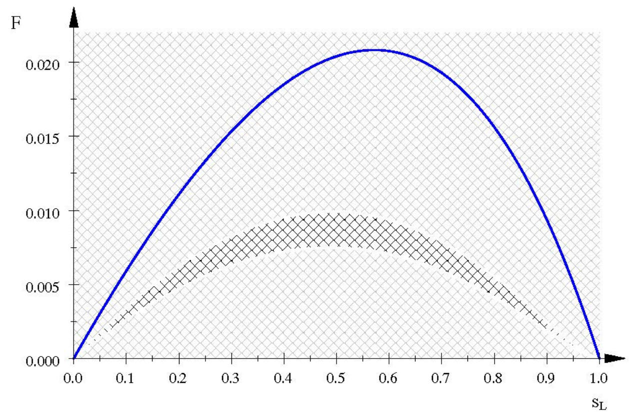
(iii) if $F < F^{**}(s_L)$ consumers prefer no early entry whereas the industry prefers early entry.

Incentives of consumers and industry are never aligned in favor of early entry agreements in a repeated entry game with Δ sufficiently small, and early entry agreements always make consumers worse off.

The dark shaded area in *figure 3* shows the combinations of fixed costs F and entrant's quality s_L, where the incentives of the industry and consumers coincide.[16] In this area $F^{**}(s_L) < F < F^*(s_L)$ and incentives of consumers and industry are aligned in favor of early entry. The solid concave line represents $\overline{F}(s_L)$.

[16]Note that for readability all of the following figures represent the per period results. Since those are just a rescaled version in terms of the interest rate r, only the absolute but not the relative level is affected.

Figure 3: Industry and consumer incentives - Bertrand



For a complete proof of the welfare and consumer surplus result in a repeated game setting, refer to the appendix.

4.2.3 Normative aspects

After having established that welfare is highest in a regime with early entry, where one single generic firm enters the market, we are examining what the optimal generic price would be in such a regime. In order to do so, we are computing the best response functions for profit, consumer surplus and welfare. The maximization of this welfare function with respect to the entrant's price p_i gives the optimal entrant's price p_i^{opt}. A detailed proof can be found in the appendix.

It can be shown that for any s_L, the equilibrium entrant's price is strictly lower than the welfare maximizing entrant's price. To see this we compare the equilibrium entry price p_i^* as defined in the model to the welfare maximizing price p_i^{opt}. Thus

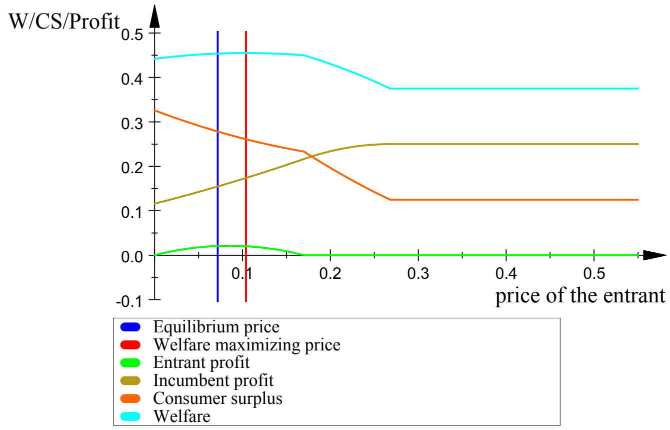
$$p_i^* < p_i^{opt} \iff \frac{s_L(1-s_L)}{4-s_L} < \frac{s_L(1-s_L)}{4-3s_L}$$

This is satisfied for any $s_L \in (0,1)$ and is represented in *figure 4*. In the figure, we chose $s_L = 4-2\sqrt{3}(\approx 0.53)$, corresponding to the quality level where the equilibrium price of the entrant in the single entry case ($p_i = \frac{s_L(1-s_L)}{4-s_L}$) is maximum.

This result has important policy implications. It suggests that despite being considerably cheaper than branded drugs, generic drugs are too expensive. Under our model of vertical differentiation, it would be welfare enhancing to increase the price of generic medicines. It should however be stressed again that the pharmaceutical market is somewhat of an unconventional market and that the market specificities make an extrapolation into a policy recommendation more difficult. Consumption behavior is distorted since consumers often do not pay the totality of the drug price (except for over the counter drugs) and the drug expenses weigh heavy on social security budgets. At the same time, the producer surplus from increased welfare is not always optimally redistributed into the economy, i.e. into research and development of new drugs. Pharmaceutical companies often spend as much into R&D than they do into marketing.[17]

[17] insert reference

Figure 4: Best response functions



4.3 Quantity competition

Instead of competing in prices, firms may choose to compete in quantities. Cournot competition may be better suited for a certain category of drugs, where firms have less influence on the price. This may for example be the case for prescription drugs, where the regulator heavily influences the price. Firms then compete in output and capacity rather than in prices. Cournot competition is typically less intense than Bertrand competition, leading to higher prices.

In the same manner as we did for Bertrand competition, we are solving for monopoly, single generic entry and the multiple generic entry. Cournot competition leads to higher prices than Bertrand competition, where prices are equal to marginal costs. Thus, Cournot competition allows for more than two entrants, but not infinitely many. In fact, a Cournot market always comes to a saturation point where the entry of one additional firm makes all competitors' profits becomes negative. We are solving the multiple entrants case for n entrants.

We use the demands of the incumbent D_I and the entrants D_i as found by considering the preferences of the consumers, to find the inverse demand functions.

Monopoly: If the incumbent stays a monopolist on the market, we have the following inverse demand function

$$D_I = q_I = 1 - \frac{p_I}{1} \iff p_I = 1 - q_I$$

By revenue maximization we get the following equilibrium price, quantity and revenue

$$q_I = \frac{1}{2}, p_I = \frac{1}{2} \text{ and } R_I = \frac{1}{4r}$$

resulting in consumer surplus and welfare

$$CS^m = \int_0^\infty \int_{\theta^{***}=\frac{1}{2}}^1 \theta s_I p_I^m d\theta = \frac{1}{8r} \text{ and } W^m = CS^m + R_I^m = \frac{3}{8r}.$$

Competition: The same exercise can be repeated with multiple entrants going from $i = 1$ to n

$$D_I = q_I = 1 - \frac{p_I - p_i}{1 - s_L} \iff p_I = 1 - q_I - s_L \sum_{i=1}^{n} q_i$$

$$\sum_{i=1}^{2} D_i = \sum_{i=1}^{n} q_i = \frac{p_I - p_i}{1 - s_L} - \frac{p_i}{s_L} \iff p_i = s_L \Big(1 - q_I - \sum_{i=1}^{n} q_i \Big)$$

Maximizing the incumbent's and entrant's revenue functions, we get the following reaction functions

$$\max_{q_I} p_I q_I \iff q_I = \frac{1}{2} \Big(1 - s_L \sum_{i=1}^{n} q_I \Big)$$

$$\max_{q_i} p_i q_i \iff q_i = \frac{1}{2} \Big(1 - q_I - \sum_{\substack{j=1 \\ i \neq j}}^{n-1} q_j \Big)$$

Solving for the system, we get the following equilibrium quantities, prices and revenues

$$q_I = \frac{1 + n(1 - s_L)}{2 + n(2 - s_L)}, p_I = \frac{1 + n(1 - s_L)}{2 + n(2 - s_L)} \text{ and } R_I = \frac{1}{r} \left(\frac{1 + n(1 - s_L)}{2 + n(2 - s_L)} \right)^2$$

$$q_i = \frac{1}{2 + n(2 - s_L)}, p_i = \frac{s_L}{2 + n(2 - s_L)} \text{ and } R_i = \frac{s_L}{r[2 + n(2 - s_L)]^2}$$

This leads to following consumer surplus and welfare

$$CS = \int_0^{\infty} \int_{\theta^*}^{\theta^{**}} \theta s_L - p_i d\theta + \int_{\theta^{**}}^{\bar{\theta}=1} \theta s_I - p_I d\theta \text{ and } W = CS + R_I + nR_i - nF.$$

where $\theta^* = \frac{p_i}{s_L}$ and $\theta^{**} = \frac{p_I - p_i}{s_I - s_L}$.

Duopoly: Now, in case of single entry ($n = 1$), these function become

$$q_I^d = \frac{2 - s_L}{4 - s_L}, p_I^d = \frac{2 - s_L}{4 - s_L} \text{ and } R_I^d = \frac{1}{r} \left(\frac{2 - s_L}{4 - s_L} \right)^2$$

$$q_i^d = \frac{1}{4 - s_L}, p_i^d = \frac{s_L}{4 - s_L} \text{ and } R_i^d = \frac{s_L}{r(4 - s_L)^2}$$

$$CS^d = \frac{s_L - s_L^2 + 4}{2r(4 - s_L)^2} \text{ and } W^d = CS^d + R_I^d + R_i^d - F.$$

Triopoly: In case of double entry ($n = 2$), we have

$$q_I^c = \frac{3 - 2s_L}{2(3 - s_L)}, p_I^c = \frac{3 - 2s_L}{2(3 - s_L)} \text{ and } R_I^c = \frac{1}{r} \left(\frac{3 - 2s_L)}{2(3 - s_L)} \right)^2$$

$$q_i^c = \frac{1}{2(3 - s_L)}, p_i^c = \frac{s_L}{2(3 - s_L)} \text{ and } R_i^c = \frac{s_L}{r[2(3 - s_L)]^2}$$

$$CS^c = \frac{9 + 4s_L - 4s_L^2}{8r(3 - s_L)^2} \text{ and } W^c = CS^c + R_I^c + 2R_i^c - 2F.$$

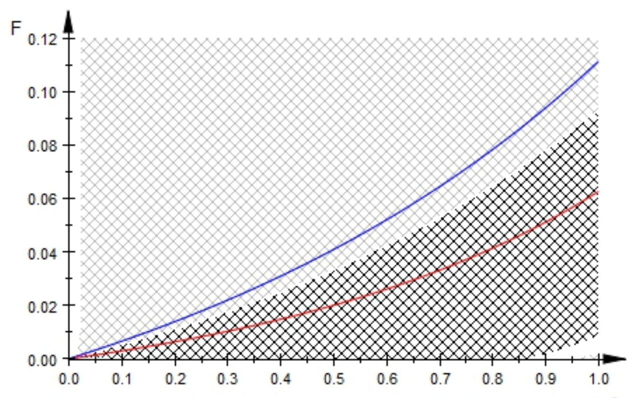
4.3.1 Welfare results

Contrary to Bertrand competition, there is no fighting effect in Cournot competition. Upon entry of one generic onto the market, the former monopolist is no longer able to expand its market share, but has to give up some shares to the entrant and less consumers are served the high quality good, resulting in a welfare loss. As the total market size is however expanding, welfare is increasing upon entry as long as fixed costs are not too large. After a certain threshold of F, the entrant is still entering the market ignoring the welfare loss resulting from people switching away from the incumbent (remember that in Bertrand, we do not have any loss, since the incumbent is expanding its market share upon entry of the generic).

Upon entry of the second generic onto the market, the incumbent's market share is further shrinking (resulting in a welfare loss), whereas total market size is again increasing (resulting in a welfare gain). Setting $F = 0$, the welfare loss exceeds the welfare gain only for s_L sufficiently small, in which case - against conventional beliefs - welfare in duopoly exceeds welfare in competition. When s_L is small, the welfare gain derived from newly gained consumers at the bottom end of the distribution is very limited. As s_L increases, the s_L slope becomes steeper and the welfare gain area expands. This is contrary to the Bertrand case, where welfare in duopoly is always higher than welfare in competition as in the former case, although less consumers are served overall, more consumers are served the high quality good. Introducing fixed costs, the intuitive conclusion of a fixed cost effect holds; since competition deduces F twice instead of once in duopoly, welfare is negatively affected. For any F is the feasibility region, welfare in duopoly exceeds welfare in competition.

Thus, in the one-shot game, welfare in duopoly exceeds welfare in mixed strategy whenever F is sufficiently small, where in addition to the effects described above, the probability of monopoly is small. Note that this aligned with the area where the incumbent is in favor of early entry as, given the high probability of entry, this avoids an otherwise competitive situation.[18] In the infinite game, as we have seen the possibility of ending up in a monopoly has been eliminated, leaving us comparing duopoly to competition. Consequently, welfare in duopoly is always higher than welfare in the mixed strategy. These results are summarized in *table 1*.

Figure 5: Welfare effects - Cournot



[18] To be precise, the area where early entry is desirable both from an industry and welfare point of view, is only so slightly smaller than the area where early entry is welfare enhancing.

The area where early entry agreements are welfare enhancing is determined by critical values of fixed costs $F^{***}(s_L)$ such that $\underline{F}(s_L) < F^{***}(s_L) < \overline{F}(s_L)$ and where $F^{***}(s_L)$ solves $\mathbb{E}[W] = W^d$, i.e. the values for which welfare in early entry is equal to welfare in the mixed strategy. These values are represented in the dark-shaded area in *figure 5*. Early entry agreements are thus only desirable from a welfare perspective if fixed costs are low enough. If the entry game is repeated with the time between periods Δ being sufficiently small, and the monopoly outcome being an unstable one, we now have that $W^d > \mathbb{E}[W]$ for any levels of F.

Table 1: Bertrand vs. Cournot

	Bertrand	Cournot
$F = 0$	$W^d > W^m$ $W^d > W^c$	$W^d > W^m$ $W^d > W^c$ for $s_L \in (0, \frac{15-\sqrt{161}}{8})$ $W^c > W^d$ otherwise
$F \in (\underline{F}(s_L), \overline{F}(s_L))$	$W^d > W^m$ $W^d > W^c$	$W^d > W^m$ for small F $W^m > W^d$ otherwise $W^d > W^c$
Result one-shot game	$W^d > \mathbb{E}[W]$	$W^d > \mathbb{E}[W]$ for small F $\mathbb{E}[W] > W^d$ otherwise
Result infinite game	$W^d > \mathbb{E}[W]$	$W^d > \mathbb{E}[W]$

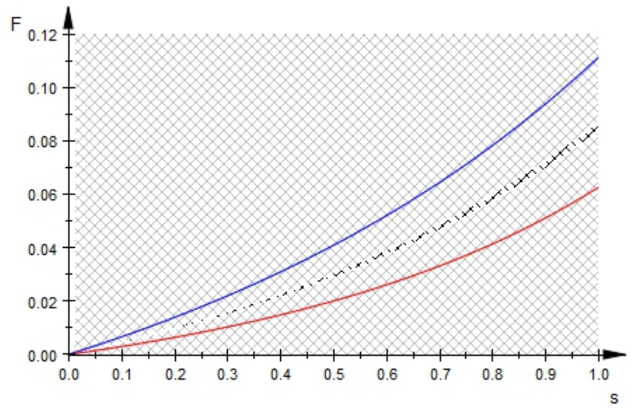
Proposition 4. *There exists a level of fixed costs $F^{***}(s_L)$ below which, allowing for early entry agreements is welfare enhancing. If the entry game is repeated and the time between periods Δ is sufficiently small, early entry agreements are welfare enhancing for any $F \in (\underline{F}(s_L), \overline{F}(s_L))$.*

4.3.2 Industry and consumers' incentives

When moving from monopoly to duopoly and triopoly, the incumbent's demand is consistently diminishing. More competition leads to lower prices and profits both for the incumbent and entrants. Thus, $R_I^m > R_I^d > R_I^c$ and $R_i^d > R_i^c$. The incumbent prefers a regime with early entry whenever $\Pi_I^d > \mathbb{E}[\Pi_I]$. This is the case for low values of fixed costs F, where the likelihood of double entry is high. The area where the industry prefers early entry is determined by the values of $F < F^*(s_L)$, where $F^*(s_L)$ solves $\mathbb{E}[\Pi_I] = R_I^d + R_i^d - F$, where the incumbent is indifferent between early entry and the mixed strategy. If the entry game is repeated and with Δ sufficiently small, the industry is always in favor of early entry since only the duopoly and competition outcomes are stable in the long run.

Since $CS^c > CS^d > CS^m$, consumer prefer early entry over mixed entry whenever the likelihood of a monopoly outcome is high. Again, there exists an area where the incentives of industry and consumers meet in favor of early entry. These values are represented in the dark-shaded area in *figure 6*.

Figure 6: Industry and consumer incentives - Cournot



Again, as in Bertrand, this area is determined by critical values of fixed costs $F^*(s_L)$ and $F^{**}(s_L)$ such that $\underline{F}(s_L) < F^{**}(s_L) < F^*(s_L) < \overline{F}(s_L)$. We know that $F^*(s_L)$ solves $\mathbb{E}[\Pi_I] = R_I^d + R_i^d - F$ and that $F^{**}(s_L)$ solves $\mathbb{E}[CS] = CS^d$. If the entry game is repeated and the time between periods Δ is sufficiently small, the monopoly outcome becomes unstable and consumers will always prefer mixed entry rather than early entry. As there is no difference in the Cournot outcome compared to Bertrand, we refer to *proposition 3* for the consumer surplus result.

5 Discussion (to be completed)

Instead of granting the right to produce a generic version of the branded drug to some independent generic company, the incumbent may opt for an in-house or licensed production to a subsidiary. The practice of authorized generics, whereby the incumbent produces the drug itself and markets it as a generic product at generic prices, is a common one, particularly in the US. However, in line with the definition of the European Commission, we are are assuming that the generic firms are truly independent producers and not subsidiaries or in-house producers of the incumbent.[19] The independency of the generic firm allows the incumbent to fully extract the generic company's rent by means of the early entry offer without incurring any fixed costs. Nevertheless, the distinction between a independent or subsidiary generic producer may be an artificial one. From a competition law perspective, as long as the (dependent) generic firm competes on the same generic market than the independent firm, it does not matter who the incumbent grants early entry to.

Our model assumes that entry costs F that both entrants incur upon entry are identical. This must not be the case, one could think of a world where one generic firm incurs higher

[19]See European Commission [9] p. 291. A note on authorized generics: contrary to the US, in the EU there is no formal status of authorized generics. In the early entry agreements discussion, the European Commission differentiates between independent generic entry and generics "launched by an affiliate of the originator company or the company itself" (see paragraph 795 Sector Inquiry). The inquiry solely focuses on the former. In the US an authorized generics is commercialized using the New Drug Application (NDA) of the originator drug, whereas independent generic must use the Abbreviated New Drug Application (ANDA). This differentiation also makes is possible that an ANDA entrant benefitting from the 180 days exclusivity under a paragraph IV patent certification can still be rivalled by an authorized generic issued by the originator but not by any other independent generic producer.

entry costs than the rival generic firm. For example, the management of a generic firm could decide to diversify the firm's product strategy and to invest into a new class of medicines. The initial investment and entry costs would then be higher than a rival generic firm active in similar markets for a long time. Stähler (1996) finds that with asymmetric entry costs, a *market entry paradox* takes place: the entry probability of a firm in a mixed strategy equilibrium decreases with the entry cost of the rival firm such that the high cost firm has higher chances of entering the market than the low cost firm, contrary to conventional beliefs. This may pose efficiency problems, since the generic firm gaining better access to the market will be the one that is least efficient. The incumbent however will respond positively to this market entry paradox (and would actually select the less efficient firm to enter (early)), as a less efficient generic competitor will be less threatening to the incumbent.

Early entry agreements seem to have received less attention than pay for delay deals. The latter, also called reverse payment patent settlements, are agreements that are reached between a patent holder and an entering firms producing a generic version of the patented product. Usually the generic producer seeks entry onto the market before patent expiry invoking non-infringement of the incumbent's patent. In order to avoid high litigation costs and lengthy jurisdictional procedures, it has become a common practice for the incumbent and concerned generic to enter into a patent settlement. This settlement specifies the date where the generic is allowed to enter (this can be before or after the patent expiry) and is often accompanied by some monetary compensation. The European Commission ranks the patent settlement agreements into two categories. Agreements in category A do not limit generic entry and therefore do not pose an anticompetitive concern. Agreements in category B are limiting generic entry in that they delay entry and can be with or without cash payments.[20] Competition authorities and scholars seem to agree that if this monetary compensation goes from the incumbent to the entrant, the settlement is very likely to be anticompetitive since the incumbent is paying the generic off in order to delay his entry.[21] If the compensation however flows from the entrant to the incumbent, the anticompetitive effects seems less likely, in particular if the entry date is still before patent expiry.

In our model there is a rent extraction by the incumbent, so we do see a flow from the entrant to the incumbent as well as entry before patent expiry. Contrary to the unconcerned conclusions in the pay for delay deals, we do believe that with early entry agreements even a monetary compensation from the entrant to the incumbent could lead to anticompetitive effects. With such an agreement the incumbent and entrant are basically agreeing on reducing competition after patent expiry. In order to benefit from lessened competition, the incumbent is willing to accept entry before patent expiry, while the entrant is willing to give up (part) of his profit.

Another crucial difference between pay for delay deals and early entry agreements is that the latter do not need to avoid any litigation about a potential patent infringement. Rather than being a resolved opposition between incumbent and entrant, early entry agreements are essentially an anticipative device that both parties use to reduce competition on the market. Rather than delaying entry which would have occurred anyways (either immediately by establishing non-infringement or later at patent expiry), early entry agreements

[20]See figure 106 on p. 270 in European Commission [9]. It should however be noted that in order to claim the correct generic entry date absent of settlements, one would need to establish the correct validity of the patent. Since settlements are precisely adopted to avoid this lengthy procedure, the categorization may prove to be difficult in practice.

[21]Insert reference

can potentially completely obstruct entry.

Our model assumes that entry by more than one generic will result in negative profits for all entering firms. This is particularly true for Bertrand competition. One might argue that in reality generic firms will still enter a market, either because there is still something to recover from the market particularly when entering firms are not necessarily symmetric in the cost structure or degree of quality or because fixed costs are already sunk. But even when not going to extremes where entry beyond a single firm is foreclosed, early entry agreements are still capable of affecting strategic decisions of the outside generic producers. The European Commission states that "The early presence of a generic product limits the attractiveness of a market for other companies as the first generic is likely to benefit from certain first-mover advantages".[22] The fact that first mover effects can be important in the pharmaceutical industry has been shown in numerous empirical studies.[23] Moreover, the vast majority of early entry agreements extend beyond the loss of exclusivity. If the agreements take the form of a supply agreement for example with fixed prices, the incumbent can extract a large portion of the generic even after patent expiry.[24]

In our application results, we have taken the very standard assumption that in a vertical differentiation model, consumers are uniformly distributed between 0 and 1. The uniform distribution is of importance when it comes to the surprising result that welfare in duopoly is higher than welfare in competition due to the accommodation effect in Bertrand competition. Thus, we might want to relax this assumption to analyze whether this strong result still holds when the distribution of consumers is other than uniform. If we think about a distribution where the majority of consumers are located at the bottom end of the distribution, there is more to loose from not serving the whole market than there is to gain by accommodating middle value consumers. Such a distribution could for example exist for some specific form of drugs or some specific populations of consumers.

Dixit and Shapiro (1986) present a model in which firms can reconsider entry and exit after their initial entry in the mixed strategy equilibrium. Thus if firms failed to coordinate, for example if they both mistakenly entered at the same time, revising their decision can achieve coordination and impose an asymmetric equilibrium. Farrell (1987) reacted to this by realizing that in some situations, for example when sunk costs are high, such coordination is unlikely and firms should rather announce their entry plans in advance of their decisions. While such cheap talk can help to achieve some form of coordination in a mixed strategy equilibrium especially if the announcement stage is repeated, it cannot coordinate the game fully as to reach an asymmetric equilibrium.

Let us reconsider our entry game. We have argued that from an institutional point of view coordination is unlikely and the unique symmetric equilibrium in mixed strategies will prevail. Now what will happen if we allow firms to reconsider exit once they (both) have entered? If we do not allow for any coordination, firms will also play a mixed strategy in this exit game and the accumulated expected payoff is zero for all firms. The entry probabilities stay the same all throughout. If we do allow for some form of coordination we must differentiate between the situation where the identity of the firm to exit is common

[22] Paragraph 809 on p. 297 in European Commission [9]

[23] insert references

[24] Paragraph 825 on p. 303 in European Commission [9]

knowledge and the situation where the firms flip a coin. In the former, coordination in the exit game leads to coordination in the entry game. If firms know that firm i will be the one to exit, i will never costly enter in the entry game. Thus, we have a pure strategy equilibrium with firm j entering and firm i staying out. If the coordination takes the form of a coin flip, the expected payoff for each firm is $\frac{\Pi_i^d}{2} - F$. If that expression is negative, firms will play mixed strategy both in the exit and entry game, although the entry probability in the entry game has increased as firms want to be able to play the exit game hoping to be the one to stay. If the expression is positive, firms hope to be the one not to exit and both firms enter in the entry game leading to excessive entry.

We have shown that early entry agreements are beneficial to consumers only in the case where fixed entry costs are above a certain level. Moreover, incentives of consumers and firms are rarely aligned in favour of early entry and are never aligned if the entry game is repeated. A valid remark on this pessimistic prospect for consumer welfare of early entry agreements is that they allow generic medicines to become available before patent expiry. Consumer benefit from increased competition and lower prices at an earlier date with the agreements than without. Nevertheless, this benefit is very short lived, as we have seen that in the long run, early entry agreements may lead to less competition and thus higher prices. For early entry agreements to be beneficial to consumers in the long run, the date of entry should be early enough such that the benefits from the temporary increase in competition can outweigh the long term drawbacks from diminished competition after patent expiry. This is unlikely to be the case, as the incumbent is using early entry agreements as as device to shape competition after patent expiry. It is sufficient to engage in early entry just prior to the date of patent expiry, and the incumbent is likely to wait until the last possible moment.

6 Conclusion

to be completed

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Appendix

Welfare and consumer surplus results in the dynamic entry game

In a repeated game, firms repeat period 1 until at least one of both firms has entered. Introducing repetition into the model gives following expected consumer surplus.

Let $K = z^{*2}CS^c + 2z^*(1-z^*)CS^d + (1-z^*)^2 \int_0^\Delta CS^m e^{-rt}dt$

$$\begin{aligned}
\mathbb{E}[CS(\Delta)] &= K + (1-z^*)^2 e^{-r\Delta}\left[K + (1-z^*)^2 e^{-r\Delta}(\cdots)\right] \\
&= \frac{K}{[1-(1-z^*)^2 e^{-r\Delta}]}
\end{aligned}$$

As $\Delta \to \infty$, this result equals the one-shot result. As $\Delta \to 0$, the expected consumer surplus quickly converges to a weighted average of the absorbing states.

$$\mathbb{E}[CS(\Delta)] = \frac{z^{*2}CS^c}{[z^{*2} + 2z^*(1-z^*)]} + \frac{2z^*(1-z^*)CS^d}{[z^{*2} + 2z^*(1-z^*)]}$$

The monopoly outcome is thus eliminated as the game repetition becomes instantaneous. In terms of consumer incentives, this means that the possibility of no competition in the mixed strategy has vanished, and the use of early entry agreements as a means to avoid monopoly has become obsolescent. In fact, the mixed strategy outcome will now always confer a (weakly) higher consumer surplus than the early entry outcome. As we have seen, this is not the case for the industry, that is always better off with early entry agreements as $\Delta \to 0$. With repetition, expected welfare becomes

Let $L = z^{*2}[\Pi_I^c + \mathrm{CS}^c] + 2z^*(1-z^*)[\Pi_I^d + \mathrm{CS}^d] + (1-z^*)^2 \int_0^\Delta [\Pi_I^m + \mathrm{CS}^m] e^{-rt}dt$

$$\begin{aligned}
\mathbb{E}[W(\Delta)] &= L + (1-z^*)^2 e^{-r\Delta}\left[L + (1-z^*)^2 e^{-r\Delta}(\cdots)\right] \\
&= \frac{L}{[1-(1-z^*)^2 e^{-r\Delta}]}
\end{aligned}$$

As $\Delta \to \infty$, this result equals the one-shot result. As $\Delta \to 0$, the expected welfare quickly converges to a weighted average of the absorbing states.

$$\mathbb{E}[W(\Delta)] = \frac{z^{*2}[\Pi_I^c + \mathrm{CS}^c]}{[z^{*2} + 2z^*(1-z^*)]} + \frac{2z^*(1-z^*)[\Pi_I^d + \mathrm{CS}^d]}{[z^{*2} + 2z^*(1-z^*)]}$$

Since welfare in the monopoly outcome is strictly lower than welfare in any competitive outcome, the welfare proposition does not change in a repeated game. Welfare in single entry is higher than welfare in double entry, and early entry agreements remain thus always welfare enhancing.

Proof Normative aspects

Maximizing the incumbent's profit function with respect to its price, we get the following best response functions

$$p_I^{BR} = \begin{cases} \frac{(1-s_L)}{2} + \frac{1}{2}p_i & \text{if } p_i < \frac{s_L(1-s_L)}{(2-s_L)} \\ \frac{p_i}{s_L} & \text{if } p_i \in \left[\frac{s_L(1-s_L)}{(2-s_L)}, \frac{1}{2}s_L\right] \\ \frac{1}{2} & \text{if } p_i > \frac{1}{2}s_L \end{cases}$$

$$\Pi_I^{BR} = \begin{cases} \frac{1}{4}\left[(1-s_L) + 2p_i + \frac{p_i^2}{(1-s_L)}\right] & \text{if } p_i < \frac{s_L(1-s_L)}{(2-s_L)} \\ \frac{p_i}{s_L}\left(1 - \frac{p_i}{s_L}\right) & \text{if } p_i \in \left[\frac{s_L(1-s_L)}{(2-s_L)}, \frac{1}{2}s_L\right] \\ \frac{1}{4} & \text{if } p_i > \frac{1}{2}s_L \end{cases}$$

where the thresholds for p_i are found by evaluating the incumbent's profit best response function at $p_I = \frac{p_i}{s_L}$, i.e., at the point where the incumbent engages in limit pricing. If the entrant's price increases any further, the incumbent becomes a monopolist. The curvature of these profit functions allows us to ensure we are maximzing and not minimizing profit. The demand functions can now be expressed as

$$D_I^{BR} = \begin{cases} \frac{1}{2} + \frac{p_i}{2(1-s_L)} & \text{if } p_i < \frac{s_L(1-s_L)}{(2-s_L)} \\ 1 - \frac{p_i}{s_L} & \text{if } p_i \in \left[\frac{s_L(1-s_L)}{(2-s_L)}, \frac{1}{2}s_L\right] \\ \frac{1}{2} & \text{if } p_i > \frac{1}{2}s_L \end{cases}$$

and

$$D_i^{BR} = \begin{cases} \frac{1}{2} - \frac{p_i(2-s_L)}{2s_L(1-s_L)} & \text{if } p_i < \frac{s_L(1-s_L)}{(2-s_L)} \\ 0 & \text{if } p_i \in \left[\frac{s_L(1-s_L)}{(2-s_L)}, \frac{1}{2}s_L\right] \\ 0 & \text{if } p_i > \frac{1}{2}s_L \end{cases}$$

In order to compute the consumer surplus it is necessary to compute the consumption thresholds

$$\theta^{**BR} = \frac{1}{2} - \frac{p_i}{2(1-s_L)} \text{if } p_i < \frac{s_L(1-s_L)}{(2-s_L)}$$

$$\theta^{***BR} = \begin{cases} \frac{p_i}{s_L} & \text{if } p_i \in \left[\frac{s_L(1-s_L)}{(2-s_L)}, \frac{1}{2}s_L\right] \\ \frac{1}{2} & \text{if } p_i > \frac{1}{2}s_L \end{cases}$$

The consumer surplus function is also defined piecewise

$$CS^{BR} = \begin{cases} \int_{\theta^* = \frac{p_i}{s_L}}^{\theta^{**}} (\theta s_L - p_i)\ d\theta + \int_{\theta^{**}}^{1} (\theta \cdot 1 - \frac{(1-s_L)}{2} - \frac{1}{2}p_i)\ d\theta & \text{if } p_i < \frac{s_L(1-s_L)}{(2-s_L)} \\ 0 + \int_{\theta^{***} = \frac{p_i}{s_L}}^{1} (\theta \cdot 1 - \frac{p_i}{s_L})\ d\theta & \text{if } p_i \in \left[\frac{s_L(1-s_L)}{(2-s_L)}, \frac{1}{2}s_L\right] \\ 0 + \int_{\theta^{***} = \frac{1}{2}}^{1} (\theta \cdot 1 - \frac{1}{2})\ d\theta & \text{if } p_i > \frac{1}{2}s_L \end{cases}$$