Market approval and strategic interactions between neighboring countries.

Abstract. This paper analyses the strategic interactions between European countries concerning market approval of drugs and pesticides by mutual recognition. This last one may create competition among countries, which through this system, are interdependent, leading them to act strategically. In order to tackle this issue, we focus on both welfare maximising and fees maximising by using a model with a single multinational firm that wishes to introduce a single "good or bad" product that generates value in the market where it is introduced and two countries which must review this product. Firstly, where countries target accuracy rates and no fees are charged, we find that, mutual recognition (welfare) strictly dominates No Mutual Recognition. If countries target welfare, then No Mutual Recognition dominates mutual recognition when fees are set to zero. Next, when the regulator optimally sets a high fee and so attracts only good firms, we also show, the welfare from a fee system without mutual recognition is higher than a system that simply maximises welfare but charges no fee. Finally, Mutual recognition and a system where the countries only maximise fee income net of the cost of review results in lower fee and either laxer review or stricter review, depending on a low or high prior belief.

JEL classification: L51, L65

Key words: welfare maximizing, fees maximizing, mutual recognition, review process

1. Introduction

Pharmaceutical and agrochemical firms must previously to marketing a new product, seek approval for their patented products by applying for a market approval (MA) to an office of regulation. It consists to prove quality, efficiency and safety of drugs and pesticides.
In Europe, these procedures are investigated by European or national authorities. In the case of pesticides, active ingredients are approved at European level and the pesticides formulation at national level, with mutual recognition. In the case of drugs, market approval can be granted either at European level or at national level and, where appropriate, by mutual recognition.

In this paper we focus on the strategic interactions between offices of regulation concerning market approval (MA) of drugs and pesticides. The existence of these strategic interactions may arise from the existence of mutual recognition system. Under the MA by mutual recognition, the owner of intellectual property submits his product for MA in one country (the rapporteur country) and by mutual recognition in other countries. If the rapporteur country grants approval, the product is automatically approved in the other countries unless they object. This system bound each country to others, and therefore may create competition among the agencies, leading them to act strategically.
Especially, agencies may compete in terms of "accuracy of the review" or in terms of "fees of the review". Furthermore, a possible race to the bottom may result from an accuracy competition (Copeland and Taylor, 2003; Javorcik and Wei 2004) or from a fee competition (Hines, 2005; Razin and Sadka, 2006) between countries.

We tackle these issues using a model a single, multinational firm wishes to introduce a single product that generates value in the market where it is introduced and two countries which must review this product. To begin, the regulator in each country chooses simultaneously and independently its level of accuracy. Next, the firm chooses where to submit its product for approval, and then the approval process occurs, resulting in an approval decision in each country. At last, the product is introduced where it has been approved and values/welfare/payoffs are earned. We find firstly, Mutual Recognition (welfare) strictly dominates No Mutual Recognition where agencies that target accuracy rates and no fees are charged. If agencies target welfare, then No Mutual Recognition dominates mutual recognition when fees are set to zero. The intuition for the proposition is that mutual recognition creates strategic interaction between the two countries, with each country wishing to free ride on the other's regulatory process. Where the quality of review can vary, this free riding incentive is so strong that it depresses the quality of

review to randomness. The random reviews disadvantage firms with good products, in turn, which reduces their innovation incentives. Where the quality of review cannot vary, the mutual recognition process has the advantage of saving on review costs. Since free riding is not possible when quality of review is fixed, this advantage dominates in the ranking of the processes.

Assuming that there is no change in fees, we also show that a system of mutual recognition and regulatory agencies that maximise fee income net of the cost of regulatory review will raise innovation incentives compared to a system that has no mutual recognition. While it would be the case that competition for applications generates both a lower fee and laxer review in some cases, it could also generate stricter review if it is very likely that the firm is high quality, and then competition for its business will take the form of lowering the fee but raising the strictness of review. In fact, with mutual recognition, there is competition that drives down the fee. This helps the firm (and so improves innovation incentives), all else equal, as it allows even the high quality firm faced with a system that attracts only high quality firms and charges a high fee, to retain some surplus. In other words, a high quality firm facing high fees would have all profits extracted in one market, but would be allowed to retain these profits from the second market. Hence, innovation incentives rise in such a system. Moreover, when we let the fees (and accuracies of the systems) vary, the firm will submit to the system that maximises its revenues net of costs from the entire submission process. The competition for business will drive down the tax as well as the fact that the agency does not put any weight on welfare so that there is never any incentive to have an accurate review. Competition for its business will take the form of lowering the fee but may raise the strictness of review. Taking a case where the firm is high quality, then the benefit of stricter review is the change in the level of accuracy times the value to the high firm of commercialising its product. The cost of doing this is the change in the cost of review that occurs when the level of accuracy increases slightly. As long as the benefit to the firm exceeds this increase in cost of review, there is a range of tax such that it is worthwhile for the firm to accept to be reviewed in this country and it is also worthwhile for the country to provide this stricter regulation. Clearly, tax cannot exceed the cost of review at any point, or the other country will compete away the difference. Hence, the regulator earns zero net revenue but the quality of review is high.

This process continues until the marginal cost of increasing the level of accuracy reaches the benefit to the high quality firm from the stricter review.

The rest of paper is organized as follow. Section II describes the institution of mutual recognition in the case of pharmaceuticals and pesticides. Section III develops a basic model focusing on a single firm which must made a choice between two national agencies of market approval. These agencies interact in the case of mutual recognition. Section IV presents some results either when regulator maximises welfare or fees net income of cost review.
Section V concludes the paper.

Related literature

Mutual recognition versus harmonisation

One specific feature of our model is the introduction of a separate agency with its own objective function as the regulatory body in addition to looking at nations that maximise welfare. Regarding this point, Lutz (2000) seems to show that, where welfare maximisation is the objective function of each country, mutual recognition dominates harmonization and no regulation in some sense. Lutz's model uses imperfect competition and a quality model to model regulation as a minimum quality standard and then looks at the resulting imperfectly competitive equilibrium in the industry and the welfare implications. He uses a single country framework. Suwa-Eisenmann and Verdier (2002), on the other hand, use a two-country framework and compare the properties of mutual recognition and harmonization when the two countries differ in institutional efficiency.

Screening process

Our paper is also related to the literature on designing screening processes. The basic Works on this was done by Sah and Stiglitz in a series of works (1985 JPubE, 1985 AER, 1986 AER, 1988 EJ, 1991, QJE, 1991 JEP). These papers discuss the relative merits of polyarchical organizations versus hierarchical organizations. Gehrig and al. (2000) has worked but in the case where firms must evaluate (potentially) cost-reducing R&D projects. As a note, Gehrig and al. (2000)'s model does not take into account agency issues, so it investigates only a single change compared to the earlier literature.

Forum shopping

Our setup has also some affinity to the recent literature on certification and standard setting organizations (SSO). We have a pioneer work from Lerner and Tirole (2006) concerning the role of technology standard setting authorities as certifiers. The main idea

is that the sponsor of a good application can make some concessions, as royalty-free licensing, to potential buyers and to choose an SSO friendly to his cause. They find on the one hand, a negative relationship between the extent to which an SSO is oriented to technology sponsors and the concession level required of sponsors, on the other hand a positive association between the sponsor-friendliness of the selected SSO and the quality of the standard.

Chiao and al. (2006) explore empirically standard-setting organizations' policy choices and they results are consistent with Lerner and Tirole (2006).

In the field of patent office, Régibeau and Rockett (2010) examine the link between the length of patent review and the importance of inventions. They find that, controlling for the position in the innovation cycle more important innovations are approved more quickly. Noting an increase of the number of patent applications and "bad" patents approved, Caillaud and Duchêne (2011) focus on the overload problem within the patent office and its impacts on the firm's incentive to invest in R&D and then to apply for a patent. They find that, since the examination process is imperfect, in equilibrium we have good patent applications, but also some bad applications. Indeed, given the mistakes made by examiners, the probability to obtain a patent is higher; therefore more applications are submitted to the patent office, increasing the workload of examiners, leading to more mistakes.

Atal and Bar (2010) consider applicants' incentives to search for prior art. In fact, as stipulated by the duty to disclose in the U.S., applicants must disclose the prior art information when filling for patent process. These authors show that the applicants might not be encouraged to seek for prior art, since their search intensity increases with R&D cost, and with the examiners' expected search effort.

Schuett (2011) looks at compensation of patent examiners and incentives for stringent approval as part of a "certification process". In his model, the government delegates patent examination to an examiner motivated by both extrinsic rewards such as monetary transfers and intrinsic rewards such as utility gains from making correct decisions. He shows that, when intrinsic motivation is low, monetary incentives may lead to a compensation scheme that rewards examiners for granting. But, with this scheme, examiners provide effort. He also shows that, as intrinsic motivation increases, extrinsic (monetary) incentives can be used more effectively, reinforcing the provision of effort. Under plausible conditions on the distribution of returns to innovation, the proportion of bad applications falls, resulting in higher patent quality.

Race to the bottom

The "race to the bottom" or "pollution haven" hypothesis is usually used in environmental economics. It's about the possibility that pollution- intensive multinational firms relocate to developing countries with less stringent environmental standards (Markusen et al., 1993, 1995; Copeland, 1994). Several empirical studies, including Javorcik and Wei (2004), tried to test this hypothesis. In contrast to previous works on environmental standards and policies, Javorcik and Wei (2004) have found strong evidence to support this hypothesis.

The pollution havens hypothesis is also based on the idea that comparative advantage can be determined by the fact that countries may differ in their degrees of stringency of environmental regulations. In doing so, if countries open their economies to international trade and investment, the low- stringency country, for example a less-developed country will attract more investments or try to get higher share from the world market by producing and exporting pollution-intensive goods. On the other hand, the high-stringency country will import the pollution-intensive goods from this country, (Copeland and Taylor, 2003).
In a recent paper, Ederington et al. (2004) find that for four-digit level data on the USA imports, exports and production over the period 1972–94, no evidence that domestic production of pollution-intensive goods in the U.S. is being replaced by imports from overseas.

Separate from forum shopping/race to the bottom issues is the issue of strategic filing behaviour in a single forum, brought about by the process of filing and review. This is the nature of the literature on patent offices. However, the strategic filing effects of accuracy levels or certain procedures when firms have multiple filing possibilities have not been looked at in the patent literature.

Approval process and quality of review

The final strand of literature is linked to how incentives at the approval office affect quality of review. Schuett (2011) looks at compensation of patent examiners and incentives for stringent approval as part of a "certification process". In his model, the government delegates patent examination to an examiner motivated by both extrinsic rewards such as monetary transfers and intrinsic rewards such as utility gains from making correct decisions. He shows that, when intrinsic motivation is low, monetary incentives may lead to a compensation scheme that rewards examiners for granting. But, with this scheme, examiners provide effort. He also shows that, as intrinsic motivation increases, extrinsic (monetary) incentives can be used more effectively, reinforcing the

provision of effort. Under plausible conditions on the distribution of returns to innovation, the proportion of bad applications falls, resulting in higher patent quality.

3. The mutual recognition system in Europe: the case of Pharmaceutical and Agrochemical products

The market approval by Mutual recognition system is one the initiatives adopted by the countries of the European Union (EU) to accelerate the regulatory approval process. It guarantees free movement of goods and services between the EU Member States. Goods which are lawfully approved in one Member State should be allowed to be approved in any other Member State, even when these goods do not fully comply with the technical rules of the Member State of destination. However, pharmaceutical and agrochemical products, which are overriding for the environmental and health safety, are subject to strict conditions.

Market approval by mutual recognition for pharmaceutical products

The mutual recognition for drugs is laid down in the *Directive 75/319/EEC*. It grants market approval in all Member States because of the grant by one Member State. It takes into account all drugs, with the exception of biotech drugs. The European Medicines Agency (EMEA) is not concerned by this process, but only if the recognition works well. Otherwise, if there are important objections, the EMEA is informed and the Committee for Proprietary Medicinal Products (CPMP) [1] gives his opinion which will lead to a decision of this Committee. This decision will be binding on all member states. Thus, the diagram of the process can be summarised as follows:

- *The filing of the drug for market approval to a rapporteur country.*

(1) The **Committee for Medicinal Products for Human Use** (CHMP), formerly known as **Committee for Proprietary Medicinal Products** (CPMP), is the European Medicines Agency's committee responsible for elaborating the agency's opinions on all issues regarding medicinal products for human use.

The owner of intellectual property submits his product for market approval in one country (the rapporteur country). This rapporteur country has 120 days to give his opinion and the review report is available 90 days later.

- *The opinion of the other Member States selected by the applicant.*

The other Member States, selected by the applicant shall have a period of 90 days to recognize or refuse the market approval. However, a state that refuses to recognize the decisions of another state must justify its refusal, in order to avoid hindering the free movement of goods. That being said, it should highlight the lack of quality, safety or efficacy. This disagreement will be then, submitted to the CPMP as an arbiter. At the end of the process, the market approval granted in this context is accompanied by a Summary of Product Characteristics (SPC) that is identical for each Member State.

- *Arrangements to ensure proper operation of this system.*

There are some arrangements that are implemented by Member States in accordance with the European Commission. They ensure the proper operation of the mutual recognition system. For drugs that have already obtained a market approval, these arrangements are first a "the Pre-New Drug Submission" (Pre-NDS). In this step, the firm revises his application with the rapporteur country in order to assess the likelihood of success or failure of market approval by the mutual recognition. In short, the Pre-NDS can highlight some parts of the application to improve. Next, there exists a *Mutual Recognition Facilitation group,* which holds monthly meetings between representatives of the Members States.

The following diagram summarises the mutual recognition process of pharmaceutical products in the EU Member States.

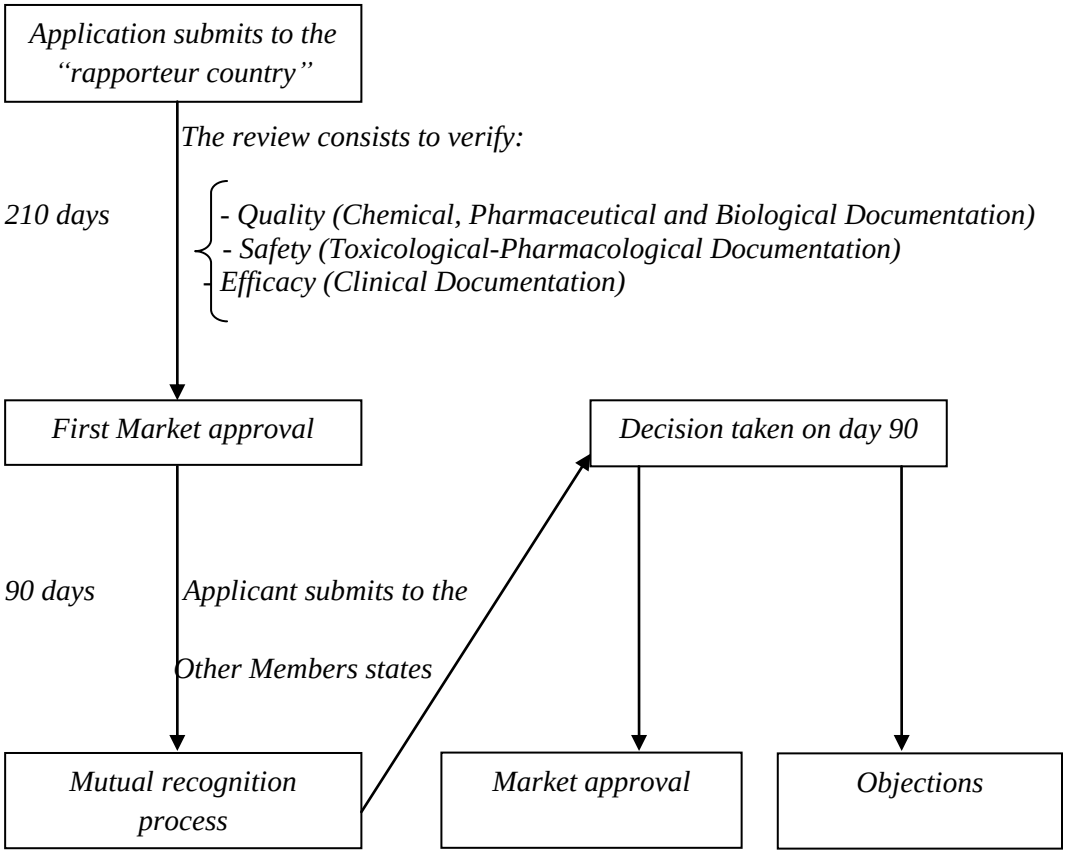

Figure 1: Mutual recognition process of pharmaceutical in the EU Member States

Market approval by mutual recognition for agrochemical products

For the agrochemical products, active ingredients are approved at European level and the pesticides formulation at national level, with mutual recognition between countries of the same zone.

Indeed, the European Union has set up recently (in June 2011) mutual recognition system between countries of the same zone. This system means an applicant can quickly receive an approval of his product if it has already been approved, either in the zone or in another zone. Mutual recognition of plant protection products concerns all market approval in a Member State, which were either granted under *Directive 91/414/EEC* in accordance with Annexes II, III and VI of that Directive or under *Regulation 1107/2009*.

- *The main zones*

The EU countries are now divided into three zones in which Member States have similar conditions. The expected benefits are a reduction of administrative charge and a wider availability of pesticides for European farmers. The main zones of market approval of plant protection products are:

Zone A - North: Denmark, Estonia, Latvia, Lithuania, Finland, and Sweden.
Zone B - Centre: Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom.
Zone C - South: Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, and Portugal.

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- *The filing of the drug for market approval to a rapporteur country of the zone*

The applicant submits for market approval in the country or countries where it wishes to place its product on the market, after the approval of the active substance and its inclusion on the EU positive list. It proposes a State to review the application. It will review this application for the whole zone (with the collaboration of other states) within 12 to 18 months. In France for example, applicant submits its product for market approval to the DGAL (Direction générale de l'alimentation) which a department of the French Ministry of Agriculture and Fisheries. This submission contains both toxicological and biological documents. The Toxicological document gives information on the safety of the pesticide for both humans (user and consumer) and environment (fauna, flora, habitats).The biological document gives information on the efficacy and selectivity of the pesticide on crops. Thus, to obtain market approval in France, applicant must prove the safety and efficacy of its product.

- *The opinion of the other Member States of the zone*

Once both the review report and the approval decision in the first Member State available, other Member States have 120 days to decide. They may refuse only on the basis of considerations regarding risks which must be justified. This system of mutual recognition is valid within the same zone and even between zones.

The following diagram summarises the mutual recognition process of pharmaceutical products in the EU Member States.

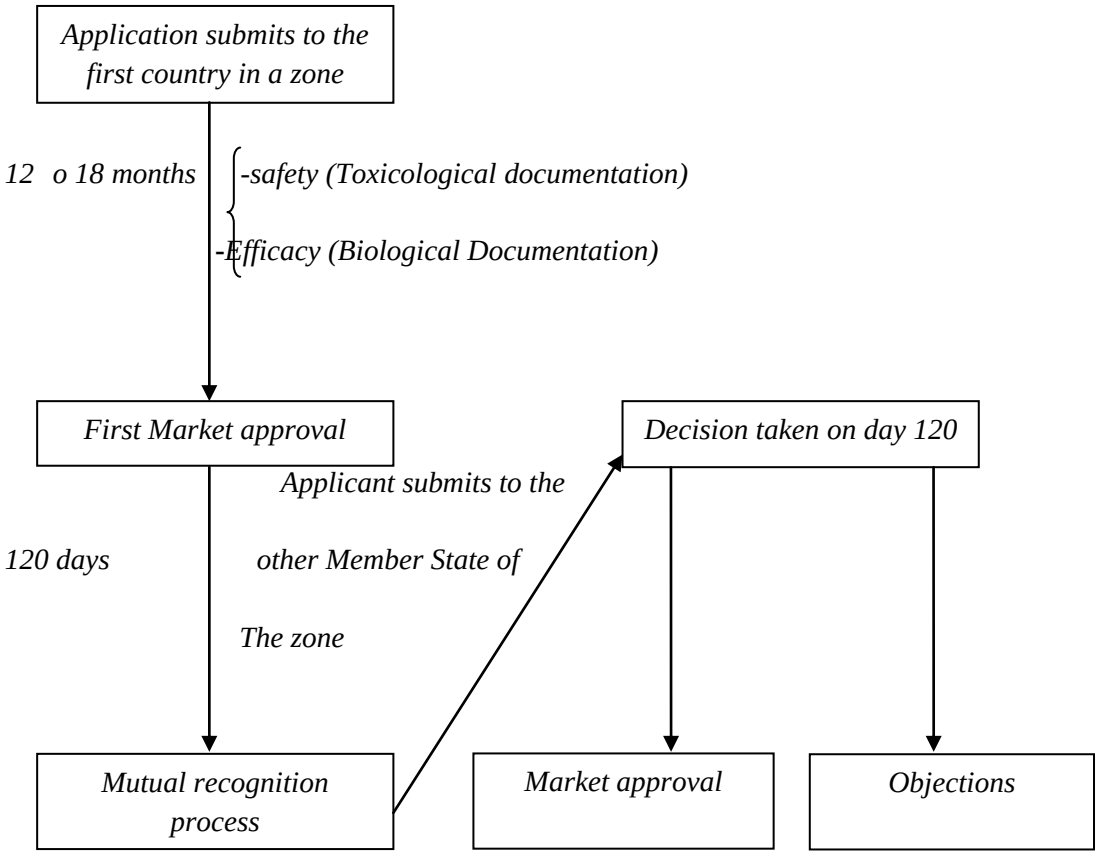

Figure 2: Mutual recognition process of plant protection products in the EU Member States

4. The model

We consider a model consisting of two countries $i=(1,2)$ and a single multinational firm, wishing to introduce a single product that generates value υ in the market where it is introduced. The variable υ can take one of two values $[\upsilon_l, \upsilon_h]$ i.e. $\upsilon=[\upsilon_l, \upsilon_h]$ with $\upsilon>0$. The firm knows that the true value of the good is υ_h, but the regulators in each country do not.

The product can also generate social welfare, W, in each country. This social welfare can take one of two values $W=[W_l, W_h]$, where $W_l<0$ and $W_h>0$. As a result, there is an incentive for each country to institute a regulatory process that approves the product for introduction. Ideally, the inspection would only approve "h" products, which generate a positive social surplus.

Unfortunately, the regulatory process is imprecise. In each country, then, the inspection generates a signal of the product's true value, where the probability that the signal is "correct" is $p_i, i=(1,2)$. In other words, p_i is both the probability that a good product i.e. υ_h is approved and the probability that a bad product i.e. υ_l is rejected. Similarly, $1-p_i$ is the probability of an "incorrect decision". Notice that these are conditional probabilities i.e. p_i is the probability that a product is judged high quality given that it truly is high quality or the probability that a product is judged low quality given that it truly is low quality.

Draws are independent across countries, so that it is possible that the product is approved in one country and not in the other. It has to be assumed that the product's true quality is not readily obvious in the marketplace upon use. In doing so, we must assume that the product generates its level of value for a number of years. In other words, just leaving the product to the market and then pulling it off the market as soon as it has revealed its true value is not a possibility for the moment: we will assume that "the damage is done" quickly enough that υ_h or υ_l is realised before the product can be pulled[1].

The cost of the regulation depends on the accuracy of the process. Especially, More or less thorough and lengthy examinations can occur: a cursory look is not accurate but is cheap and quick. Hence, we have the cost of review being $c(p_i)$, where $c'(p_i)>0$ and $c''(p_i)>0$ as well for $p_i > 1/2$, so that it becomes more expensive to add increments of accuracy as the process itself becomes more precise. Indeed, becoming absolutely sure of the quality before introduction is prohibitively expensive.

If a product is rejected, the firm earns zero. If a product is accepted, it is introduced and the firm earns its value and society collects its welfare value. Hence, approval precedes introduction.

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(1) As an example, we can think of the recently approved and marketed fertiliser by DuPont in the USA. This fertiliser, to be used for lawns, also has the negative side effect of killing maple trees. This was not spotted by regulators during approval and so the product was marketed. It has since done a great deal of damage to maple trees in the areas where it is used. I do not know the current status of the product. Other products that can have quick negative effects in the history of such approvals are a variety of drugs (thalidomide being the most famous case). Clearly, the fear about approving GM crops for introduction was precisely that they would do damage upon introduction and so the regulatory decision was not easily "reversible" in the case of a mistake. All the regulatory processes that have led to these products are imprecise processes that attempt to discover the true nature of a product before its introduction, precisely to prevent such mishaps. Many countries have such processes. The independence of the draws clearly is a controversial assumption that can be explored.

Furthermore, two different forms of approval process are possible, in particular no mutual recognition, where each country simultaneously and independently reviews the product for introduction in the country; and mutual recognition, where a single country reviews the product and its decision regulates both countries' introduction decisions.

The regulator chooses the level of accuracy, p_i, and the firm chooses where to submit its product for approval.

In other words, the sequence of decisions is as follow: firstly, the regulator in each country chooses simultaneously and independently its level of accuracy, p_i, $i = (1,2)$[2]. Secondly, the firm chooses where to submit its product for approval, and thirdly, the approval process occurs, resulting in an approval decision in each country. Finally, the product is introduced where it has been approved and values/welfare/payoffs are earned.

Note that p is not the *ex ante* probability that the product is high or low quality. Call this θ. The *ex ante* probability that the product is low quality is $1-\theta$. These probabilities do not apply to the firm: they apply only to the regulator (who doesn't know the true quality but does have these priors about the probabilities).

(2) There is full information on p_i for all parties.

5. Results

We present here, the main results depending on whether the regulator maximises social welfare or fees of review.

5.1. Welfare Maximising Regulators

Benchmark: No Mutual Recognition

We begin by assuming that each country's regulator maximises the welfare of that country. Assume first that there is no mutual recognition so that the two countries review the product at home simultaneously and independently, so that no learning from one is possible for the other and there is no correlation in decisions.

Start with no fee for regulation. In this case, the firm will certainly submit its product to any regulator that could potentially generate a market for its product since the value is certainly above zero and the regulatory process is costless from the firm's perspective.

The firm's expected payoff from a single country's regulatory process is $E_i(\upsilon) = p_i \upsilon_h$ (since the firm truly has product υ_h and knows it) and the net payoff for the regulator in that country is $E_i(W) = \theta[p_i W_h] + (1-\theta)[(1-p_i)W_l] - c(p_i)$.

Notice for later that $E_i(\upsilon)$ is strictly increasing in p_i, $E_i'(\upsilon) > 0$ and $E_i'(W)$ clearly is not. The optimal accuracy in country $i = (1,2)$ is obtained by maximising $E_i(W)$ with respect to p_i. As the firm will surely submit its product to any and all regulators, and the markets are fully independent, there is no strategic interaction between regulators so that the p_i is set independently and as a result of this maximisation only.

Hence, the optimal p_i is such that $\{\theta W_h - (1-\theta)W_l\} - c'(p_i) = 0$ or p_i^* is defined implicitly by this equation. Since $W_l < 0$, the term in curly brackets is positive. As $c'(p_i)$ is positive and increasing, we see that as the relative magnitude of a loss in welfare due to a poor product coming on the market increases, the optimal p_i^* also increases. Notice, too, that the second order conditions are fulfilled by the assumptions on $c(p_i)$. Moreover, in the absence of any fees for approval, the firm strictly prefers any

country with a higher p_i since its expected payoff is strictly increasing in p_i. Hence, the firm will submit to any country $i=(1,2)$ where $p_i^* > p_j^*, i \neq j$.

Furthermore, the maximisation of the welfare for the two countries, taken as a whole, leads both countries to set the same level of accuracy $p_i^* = p_j^* = p^*$ (see appendix). In this case, the firm submits in both countries, earning (in expectation and in fact) $2p^*\upsilon_h$. Each country earns $p^*W_h - c(p^*)$ in actual fact but earns $\theta\left[p^*W_h\right] + (1-\theta)\left[(1-p^*)W_l\right] - c(p^*)$ in expectation. Is this expression positive? In other words, is it the case that the approval procedure is worthwhile carrying out in the first place (rather than simply banning all products from being sold and earning zero)? We have to assume it is at least zero to have our problem make sense. Hence, we assume that the expected earnings are at least zero at p^*. Otherwise, we can say little about this expression at this point.

Note that there always is an incentive to create the product in the first place as long as the cost of innovation is less than $2p^*\upsilon_h$.

Lemma1. *When each country's regulator maximises the welfare of that country in the absence of any fees for approval:*

(i) *As $c'(p_i)$ is positive and increasing, the relative magnitude of a loss in welfare due to a poor product coming on the market increases, the optimal p_i^* also increases.*

(ii) *The firm strictly prefers any country with a higher p_i since its expected payoff is strictly increasing in p_i. Hence, the firm will submit to any country $i=(1,2)$ where $p_i^* > p_j^*, i \neq j$.*

(iii) *The maximisation of the welfare for the two countries, taken as a whole, leads both countries to set the same level of accuracy $p_i^* = p_j^* = p^*$.*

Mutual Recognition is legally permitted

Now, we move on to mutual recognition, where in this case we will implement this system as saying that as soon as the firm chooses a country in which to be approved, no further submission is possible (so that a negative decision in a single country cannot result in the firm's attempting submission elsewhere). All countries must abide by this "first" decision, whatever it is.

Proceed in two steps. First, assume that the regulators in both countries target an accuracy rate, p^*, rather than maximising welfare. If this is the case, and there is no fee for application, the firm is indifferent about where it submits its product for approval. The countries are not indifferent, however, as approval in the "rival" country strictly dominates approval at home: the accuracy rate is the same, so that the expected gains are the same, but at home the country must bear the cost of approval. Hence, there is a strong incentive to free ride on the other country's approval process. If p^* is fixed, there is no mechanism to free ride. For this, we must let p^* vary. That being said, if p^* remains fixed we have the result that welfare for the two countries taken as a whole strictly raises under mutual recognition. The firm is no worse off under such a system. The reason for the result is the saving in review cost.

Lemma 2[3]. *If we set* $p_i^* = p_j^* = p^*$ *or equivalently, if the regulatory agency is tasked to target accuracy rather than maximising welfare and the accuracy target is set to* $p_i^* = p_j^* = p^*$ *:*

(i) *The mutual recognition strictly dominates no mutual recognition from the perspective of world welfare and dominates no mutual recognition (but not strictly) for each individual country. Firms are indifferent and innovation incentives are not affected.*

(3) Indeed, for any arbitrary p that is targeted by the regulatory agencies, as long as p is the same across countries so that there is coordination on the level of p, this lemma will hold. The only difference is the level of welfare that is earned.

Notice that the firm, in the absence of any fees for approval, strictly prefers any system with a higher p since its expected payoff is strictly increasing in p. Hence, the firm will submit to any country $i=(1,2)$ where $p_i^* > p_j^*, i \neq j$. As a result, the Nash strategy of each (non-cooperative) country will be to undercut the other country's accuracy level ever so slightly. This is similar to a Bertrand game, in fact, with undercutting by a country so as to *avoid* approval since avoidance generates a discrete gain of $c(p)$ in net welfare. The reason there will be an incentive to undercut slightly is that there is a discrete gain with very little change in probability of approval.

This reduction in accuracy continues until the welfare from the approval process is expended entirely or $E_i(W)=0$ so that $\theta[p_i W_h]+(1-\theta)[(1-p_i)W_l]-c(p_i)=0$. Is this level of p greater or less than p^*, above? Clearly, starting at p^* for both countries, there is an incentive to cut the level of accuracy as long as, at p^*, this expression is positive. Hence, we can argue that the mutual recognition system will always lower the level of p as long as there was expected surplus from the original system at p^*, above. Call the level of p that satisfies $E_i(W)=0$, p^{**}, where $p^{**} \leq p^*$.

The firm is indifferent about where it submits but earns $2p^{**}\upsilon_h$ from the process, which is less than $2p^*\upsilon_h$, as they earned without mutual recognition. Since we have shown that $p^{**} \leq p^*$, we know that earnings must fall. Hence, the incentive to invent in the first place also falls (since the reward to invention falls).

Lemma 3. *If there are no frees for approval, the firm will submit to any country* $i=(1,2)$ *where* $p_i^* > p_j^*, i \neq j$. *Therefore:*

(i) *The Nash strategy of each (non-cooperative) country will be to undercut the other country's accuracy level ever so slightly, until the welfare from the approval process is expended entirely or* $E_i(W)=0$.

(ii) *If we call* p^{**} *the level of p that satisfies* $E_i(W)=0$*, the firm earns* $2p^{**}\upsilon_h$ *from the process, which is less than* $2p^{*}\upsilon_h$*, as it earned without mutual recognition, since* $p^{**} \le p^{*}$*. We know that earnings must fall.*

Proposition 1. *Mutual Recognition (welfare) strictly dominates No Mutual Recognition where agencies that target accuracy rates and no fees are charged. If agencies target welfare, then No Mutual Recognition dominates mutual recognition when fees are set to zero.*

The intuition for the proposition is that mutual recognition creates strategic interaction between the two countries, with each country wishing to free ride on the other's regulatory process. Where the quality of review can vary, this free riding incentive is so strong that it depresses the quality of review to randomness. The random reviews disadvantage firms with good products, in turn, which reduces their innovation incentives. Where the quality of review cannot vary, the mutual recognition process has the advantage of saving on review costs. Since free riding is not possible when quality of review is fixed, this advantage dominates in the ranking of the processes.

5.2 Fee maximising regulators

Now assume that the approval agency does not maximise welfare. Instead, it maximises fee income net of review cost. Fees are charged as a flat application fee, t_i, every time approval is sought. Hence, the net payoff from one approval event for the regulator is $t_i - c(p_i)$. The net payoff to the firm from one approval request is $E_i(\upsilon) = p_i\upsilon_h - t_i$. The expected welfare of each country is the same as before with the exception that now fee income is earned when a firm submits an application.

Benchmark: No Mutual Recognition

Under no mutual recognition, a firm will submit to a country as long as its expected payoff from submission, exceeds zero or $t_i < p_i\upsilon_h$. Notice that the regulator's payoff strictly increases in t_i, and that there is no strategic interaction between the countries when no mutual recognition exists so that, all else equal, the regulator would like to increase the fee up to the point that the firm is just indifferent between submitting or not.

The regulator does not know the value of υ_h, however, so it does not know that it can increase the fee up to $p_i\upsilon_h$. Rather, it must infer the payoff of the firm *ex ante*.

By setting the fee higher, the regulator can, however, screen the types of applications it receives: a high enough t_i will only attract good applications. The country has an incentive to do this so that t_i will be increased up to the point $t_i = p_i\upsilon_h$. If this is the case, only good applications will be submitted: the fee itself screens applicants so effectively that there is no need for an application procedure to follow it – although a review process must be conducted so as to generate approval. That being said, it is costly to raise p_i above $1/2$. Let $p_i = 1/2$ and let $t_i = .5\upsilon_h$. Will only good firms submit? If a bad firm submits, it earns $.5\upsilon_l - t_i < 0$, so it will not. Hence, we maximise the payoff by setting $p_i = 1/2$. The payoff to the regulator is $.5\upsilon_h$ in actual fact and the payoff to the firm is 0. The expected payoff for the regulator of such a scheme is $\theta[.5\upsilon_h]$. Expected welfare is $\theta[W_h + .5\upsilon_h]$. In other words, it is the welfare gain of a high product times the probability that the product actually is high (and so will be submitted), plus the fee income from the regulatory process, minus the cost of approval (which is zero since the process is completely inaccurate).

Note that the regulator collects the entire surplus and the firm is left with nothing. Unfortunately, this creates zero innovation incentives. If we take this into account, the regulator is more constrained in its fee setting. Hence, this is the solution once the product is created. It is not the solution if we fold back the game to the innovation stage.

The regulator can also set the fee low enough that any firm will submit an application. This has the disadvantage of possibly letting bad products through. We know that in this case welfare falls (since the welfare is negative for a bad product). On the other hand, the regulatory body may do better since it potentially collects fees from all comers. In other words, if the regulatory body really does not care about maximising welfare and instead just maximises revenues minus costs, then we are faced with a situation where, if it is anticipated that a lot of firms are bad, the regulator will not want to restrict fees to only induce high quality firms to submit: it may prefer to lower fees so that all submit simply because it wishes to increase fee revenues. This may, of course, raise total welfare if one

includes fee income in total welfare: the welfare loss from the bad product may be small enough that the fee income makes up for the loss.

More precisely, within the range for which all types of firm would apply, it is again optimal for the regulator to set the cost of review as small as possible and then maximise the fee. In other words, if what the regulator is trying to do is maximise $t_i - c(p_i)$, and the regulator is not attempting to screen applicants out from applying, then t is set to the maximum such that all types apply and, within this, p_i is set as close to $\frac{1}{2}$ as possible. Setting $p_i = \frac{1}{2}$ and the fee equal to $t_i = \frac{1}{2}\upsilon_l$ is the optimal scheme for attracting all comers[4].

Is the revenue from screening and only attracting good applicants better or worse than the revenue from attracting all types? $\frac{1}{2}\upsilon_l \leq or \geq \theta\left[\frac{1}{2}\upsilon_h\right]$? This is equivalent to asking whether $\upsilon_l \leq or \geq \theta\upsilon_h$ or whether $\theta \leq or \geq \frac{\upsilon_l}{\upsilon_h}$. In other words, if the likelihood that the firm is good is anticipated to be quite high, then the regulator prefers to set a high fee, attracting only good firms, and then conduct a completely random but costless review process. If the likelihood that the firm is good is quite low ex ante, then the regulator sets a low fee, attracts all comers, and still conducts a completely random but costless review process. In either case, the quality of the review falls under a scheme with fees.

Lemma 4.

(i) *For a fee maximising regulator facing a "good population" or equivalently a "high likelihood" that the applicant firm is good, defined as the probability exceeding the ratio* $\frac{\upsilon_l}{\upsilon_h}$*, the optimal scheme may be to set the fee to fully screen out a bad applicant and then have a completely random screening process to follow. The firm with a good product earns zero surplus from this system. A firm with a bad product will earn zero and will not submit an application.*

(4) Why? Suppose that, instead, we increased p_i slightly from $\frac{1}{2}$ to $\frac{1}{2}+\varepsilon$. This would mean that the optimal fee that would successfully attract all types of firm would decrease to $\left(\frac{1}{2}-\frac{1}{2}+\varepsilon\right)\upsilon_l$ and also the cost of review would increase from zero at $p_i = \frac{1}{2}$ to $c(p_i) > 0$ (for $p_i > \frac{1}{2}$). Hence, the best the regulator can do and attract all types of firm is $t_i = \frac{1}{2}\upsilon_l$ and $p_i = \frac{1}{2}$. If this is used, then the expected revenue is $\frac{1}{2}\upsilon_l$.

(ii) *Alternatively, if the ex ante probability that the applicant is good is "low", so that* $\theta \leq \upsilon_l / \upsilon_h$ *, the fee maximising regulator chooses to set the fee so that all types of applicants apply. Still, the approval process is completely random.*

Hence, we see that a fee maximising regulator lowers the quality of review, instead using the fee to conduct any screening that occurs. In other words, the fee is strictly preferred as an instrument over using the regulatory process itself to conduct screening since the regulatory process is costly and the fee is not but both may be used to conduct screening (the goal of the regulatory body in the end). Contrary to the costly regulatory process, the fee is revenue and a benefit to the regulator. Hence, the regulator may choose to do no screening whatsoever with the regulatory process and simply collect a fee from all firms that wish to sell in the country conducting effectively no quality assurance at all.

The welfare of such a system depends on whether only good firms are attracted or whether all firms are attracted. If good firms only apply, the expected welfare of such a system is $E_i(\upsilon) = \frac{\theta}{2}[W_h + \upsilon_h]$. If all firms apply, the expected welfare is $E_i(\upsilon) = \frac{1}{2}[W_l + \upsilon_l]$. Since $W_l < 0$, the second of these expressions may be negative, although the first of these expressions certainly is positive. Hence, we can say that the first of these certainly exceeds the welfare generated by the mutual recognition system when the regulators maximised welfare, but the ranking with the other systems is less clear. On the one hand, the fee system earns fee income which raises national welfare (assuming that the firm is from outside both countries so that this fee income is an inflow to the country). On the other hand, the accuracy of such a system can be very low if all comers are attracted.

Lemma 5. *Let regulators now have two instruments to screen – fees and the regulatory procedure.*

(i) *If the likelihood that a firm is a good type is high so that the regulator optimally chooses to set a high fee and so attracts only good firms, then the welfare from a fee system without mutual recognition is higher than a system that simply maximises welfare but charges no fee. The reason is that the fee income both increases welfare and serves to screen applicants more efficiently (because it is costless) than the regulatory process.*

(ii) *If the likelihood that a firm is a good type is low so that the regulator optimally chooses to set a low fee and attract all firm types, then the welfare ranking is ambiguous when comparing this system to a system with no fee but where regulators maximise welfare.*

(iii) *In this last case, the welfare maximising system works better than fees if* $c\left(p^*\right)+\frac{\upsilon_l}{2}<\theta p^* W_h-\left[\left(p^*-1/2\right)+\theta\left(1-p^*\right)\right]W_l$ *.Then, when* W_l *is a very large loss the welfare maximising system works better than fees – so that when there is a concern that a low quality firm might really damage society, and where the probability that the firm is low quality is high, the fee maximising regulator does not work well.*

(iv) *Furthermore, if the welfare maximising system regulators are able to screen with a lower cost* $c\left(p^*\right)$*, they may be better than fees system.*

In terms of innovation incentives, the fee extracts all surpluses from the high quality firm when it is set so that only the high quality firm applies. This leaves no innovation incentive for the firm. If the fee is set so that it attracts all comers, then the high quality firm does retain some surplus, although the low quality firm retains none.

Mutual Recognition is legally permitted

With mutual recognition, there is competition that drives down the fee as before. How far will the fee fall? Start from a point where the fee is high enough that only high quality firms apply. In other words, start from the no mutual recognition benchmark. If we introduce mutual recognition with no change in fees/review quality then we obtain no improvement in the cost of screening (as we did before – recall that before the gain from mutual recognition was that it eliminated one of the two screening costs, $c\left(p^*\right)$), but we do have a reduction in fees. This helps the firm (and so improves innovation incentives),all else equal, as it allows even the high quality firm faced with a system that attracts only high quality firms and charges a high fee, to retain some surplus. In other words, a high quality firm facing high fees would have all profits extracted in one market, but would be allowed to retain these profits from the second market. Hence, innovation incentives rise in such a system.

Lemma 6. *A system of mutual recognition and regulatory agencies that maximise fee income net of the cost of regulatory review will raise innovation incentives compared to a system that has no mutual recognition, assuming that there is no change in fees (so that fees are held constant at the no mutual recognition level).*

In terms of welfare (and where we continue to leave the fees the same as in the no recognition case), this need not rise because one of the two countries loses fee income, which was a welfare benefit before. Still, if the welfare is positive it must be above the level of the mutual recognition system where regulators maximised welfare, above (since that level of welfare was zero).

Suppose now that we let the fees (and accuracies of the systems) vary. Now, the firm will submit to the system that maximises its revenues net of costs from the entire submission process, which is $E_i(\upsilon) = p_i \upsilon_h - t_i$, where t_i and p_i can vary across countries. Hence, the firm compares both the revenue side (taking the probability of approval into account) and the cost side (the fee).

The countries wish to minimise the cost of review, should they have to review the product themselves, but also maximise the revenues from review. Minimising the cost of review hurts the firm by reducing the revenue side but has the benefit of cutting the cost of review for the country, should they receive the review at home. On the other hand, if regulators put the entire weight of screening on the fee, this tends to drive the fee up – and a lower fee will attract a firm as an applicant (and so will create revenue for the country).

The equilibrium in this case is that the entire process gets completely inaccurate, with $t_i = 0$ and also the process being completely random. This is because of the competition for business (driving down t_i in a Bertrand manner as before) as well as the fact that the agency does not put any weight on welfare so that there is never any incentive to have an accurate review. The essence is a Bertrand game with price competition and the ability of the firm to "choose its own marginal cost" so that the cost equals zero.

Lemma 7.

(i) Mutual recognition and a system where the agencies only maximise fee income net of the cost of review results in zero fees and no accuracy in review. Welfare is minimised of all the systems we have looked at so far.

(ii) While welfare is minimised, innovation incentives are not necessarily, as the fee no longer is used to extract all surplus from certain applicants.

While it would be the case that competition for applications generates both a lower fee and laxer review in some cases, it could also generate stricter review in others. If we take the case where it is highly likely that the firm is low quality, for example, then competition for the firm's business will take the form of both a lax review and a low fee ($p_i = 1/2$ and $t_i = 0$). The regulator earns nothing in equilibrium, but both compete for business so that the earnings go to zero. If we take the case where it is very likely that the firm is high quality, however, then competition for its business will take the form of lowering the fee but raising the strictness of review. Taking the extreme case where we know that the firm is high quality (we wouldn't need review in this case, but just supposing…) then the benefit of stricter review is the change in p_i times the value to the high firm of commercialising its product (in the two markets). The cost of doing this is the change in the cost of review that occurs when p_i increases slightly. As long as the benefit to the firm exceeds this increase in cost of review, there is a range of t_i such that it is worthwhile for the firm to accept to be reviewed in this country and it is also worthwhile for the country to provide this stricter regulation. Clearly, t_i cannot exceed the cost of review at any point, or the other country will compete away the difference. Hence, the regulator earns zero net revenue but the quality of review is above $p_i = 1/2$. This process continues until the marginal cost of increasing p_i reaches the benefit to the high quality firm from the stricter review. At that point, there are no more increments in quality of review, t_i is set to $c(p_i)$ at this level, and the firm earns expected profit based on this level of p_i and t_i.

Which of these two effects – those that raise or lower p_i – dominates depends on the ex ante probability that the applicant is high or low quality. In other words, in calculating the equilibrium quality level and fee, we would need to maximise the expected gain of the regulator in setting p_i and t_i. For a high probability that the firm is high quality, we

would expect that the p_i raising incentives would dominate and the equilibrium would have p_i above $1/2$, while for a low probability that the firm is low quality we would expect that p_i would be at or close to $1/2$.

Lemma 8.

(i) While it would be the case that competition for applications generates both a lower fee and laxer review in some cases, it could also generate stricter review if it is very likely that the firm is high quality, and then competition for its business will take the form of lowering the fee but raising the strictness of review.

(ii) For a high probability that the firm is high quality, we would expect that the p_i raising incentives would dominate and the equilibrium would have p_i above $1/2$, while for a low probability that the firm is low quality we would expect that p_i would be at or close to $1/2$.

Proposition 2:

Assuming that there is no change in fees, a system of mutual recognition and regulatory agencies that maximise fee income net of the cost of regulatory review will raise innovation incentives compared to a system that has no mutual recognition. While it would be the case that competition for applications generates both a lower fee and laxer review in some cases, it could also generate stricter review if it is very likely that the firm is high quality, and then competition for its business will take the form of lowering the fee but raising the strictness of review.

6. Conclusions

The mutual recognition system which is one the initiatives adopted by the countries of the European Union (EU) to accelerate the regulatory approval process may create competition among countries, leading them to act strategically. We use a model with a single multinational firm that wishes to introduce a single product that generates value in

the market where it is introduced and two countries which must review this product, before marketing. The regulator in each country chooses simultaneously and independently its level of accuracy. Next, the firm chooses where to submit its product for approval, and then the approval process occurs, resulting in an approval decision in each country. At last, the product is introduced where it has been approved and values/welfare/payoffs are earned.

First, we find that Mutual Recognition (welfare) strictly dominates No Mutual Recognition where agencies that target accuracy rates and no fees are charged. If agencies target welfare, then No Mutual Recognition dominates mutual recognition when fees are set to zero.

Second, when we assume that there is no change in fees, we also show that a system of mutual recognition and regulatory agencies that maximise fee income net of the cost of regulatory review will raise innovation incentives compared to a system that has no mutual recognition. While it would be the case that competition for applications generates both a lower fee and laxer review in some cases, it could also generate stricter review if it is very likely that the firm is high quality, and then competition for its business will take the form of lowering the fee but raising the strictness of review.

Given the results obtained in this paper, it would be interesting to explore either a case with continuum of firms or a case where firms don't know their type.