Trade Mark Cluttering - Evidence from EU Enlargement

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JEL: L11, L13, O34

Keywords: Trade Mark, Cluttering, Regulatory Uncertainty, Difference-in-Differences Estimator, Matching Estimator

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1 Introduction

Since the mid 1990's medical regulators in the United States and Europe regulate the names of ethical drugs.[1] The aim is to protect consumers from medication errors that result from drug name confusion. Medical journals have repeatedly reported instances of confusion deriving from similar brand names for ethical drugs (Costable Jr and McKinley, 1996; Raffalli et al., 1997). Instances of lethal medication errors due to the confusion of drug names are documented.[2]

While registering new names or signs with trade mark offices is simple, passing the scrutiny of medical regulators is much more difficult (De Benedetti et al., 2006; Wick, 2011; Lallemand, 2011). Rejection rates of invented names for ethical drugs can be as high as 40%.[3] In response, drug producers hedge their bets by submitting between three and four invented names per drug to medical regulators.[4] Creating a suite of suitable names for new ethical drugs can cost anything between US $ 100,000 and US $ 700,000 (Kenagy and Stein, 2001) and may cost up to US $ 2.25 million (Wick, 2011).

Vetting invented names for ethical drugs to prevent medication errors is clearly beneficial to consumers. However, the policy of applying for multiple names per new ethical drug is creating a negative externality. Unused trade marks in Nice classes for pharmaceutical products are raising the costs of identifying new names to be registered in these classes. A significant proportion of the costs of identifying new names for ethical drugs is due to unused registered trade marks.

Drug manufacturers usually register invented names as trade marks before these are submitted to medical regulators. In Europe, the Community trade mark office (OHIM)[5] administers the Community Trade Mark (CTM), that is valid throughout the entire territory of the European Union (EU). CTMs generally remain on the trade mark register for ten years, even if unused.[6] Unused marks

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1 An ethical drug is a drug that is available only on prescription. In the United States name regulation falls under the auspices of the FDA whilst in Europe the (Invented) Name Review Group (NRG) of the European Medicines Agency (EMA) performs this function.

2 Compare for instance the FDA's website: FDA on Medication Errors.

3 Contrast this with the 15.93% opposition rate for Community Trade Marks (CTMs) registered in Nice classes related to pharmaceuticals in the years between 1996 and 2010. CTMs are valid throughout the territory of the European Union.

4 De Benedetti et al. (2006) and Lallemand (2011) both indicate 3 or 4 invented names are created per product.

5 The **O**ffice for **H**armonization in the **I**nternal **M**arket has administered an EU wide register for trade marks since 1996.

6 Although there is a requirement that CTMS be used within five years from the date of their registration, this does not in practice affect the number of surplus trade marks at OHIM. Cancellations at OHIM before 1.3.2010 were 513 out of 302,771 marks registered before 1.1.2006. Trade marks registered after 1.1.2006 could not have been cancelled yet, because a CTM has to be put to genuine use within 5 years following registration.

clutter[7] the trade mark register, raising search costs for other trade mark applicants. Quantifying this cost is hard and no reliable estimates of it exist in the current literature.

This paper provides a first step towards such a quantification by identifying how many surplus marks there are. In March 2010 there were 150,743 CTMs in force in Nice classes closely related to pharmaceutical products at OHIM[8], with 21,574 new applications in 2009. I estimate that after 2001 6% of these marks were surplus marks.[9] Assuming that each new invented name in pharmaceuticals costs US $25,000 (which is conservative), total annual costs of inventing surplus names for EU drug applications ran at US $ 17.7 million dollars between 2001 and 2004. Since then, these costs will have increased as the number of applications has increased. A significant proportion of this cost arises because applicants cannot easily establish whether marks on the register are used.

I exploit enlargement of the European Union in 2004, when ten countries joined the EU simultaneously, to estimate the proportion of surplus trade marks currently registered as CTMs. After EU enlargement, the probability of a name surviving invented name review dropped: each accession country became a party to invented name review and each member holds a veto. To identify the effect of this regulatory shock I compare trade mark applications by pharmaceutical companies before and after 2004 with those of other firms. Two empirical methods are used to estimate the effect of the shock to invented name review in 2004: a Difference-in-Differences estimator and a nearest neighbor matching estimator proposed by Abadie et al. (2004). These two methods are complements to one another. The DiD estimator requires that common trends affected the trade mark application strategies of firms inside and outside the pharmaceuticals industry before and after 2004. The matching estimator requires that variables which affected whether a firm was a producer of ethical drugs after 2004 were either observable or had no effect on the number of trade marks the firms applied for. Arguments for the validity of both assumptions are discussed in the paper.

The paper also provides a theoretical model describing investment in pharmaceutical research and choice of the number of names submitted to a medical regulator. I assume that drug manufacturers who had sunk R&D investments prior to the determination of the date and extent of European Enlargement could only adjust to this shock by changing the number of trade marks they applied for. The model reveals that firms had incentives to apply for more trade marks after

[7] According to the Merriam Webster dictionary to clutter signifies to fill with scattered things that reduce effectiveness. von Graevenitz et al. (2012) propose the following definition of cluttered trade mark registers: cluttered trade mark registers are registers containing such a large number of unused or overly broad trade marks, that the costs of creating and registering new marks substantially increase for other applicants.

[8] As I discuss in Section 5 below these are the classes 1,3,5,10,13,44.

[9] See Appendix 8.1 for the calculations.

EU enlargement under reasonable assumptions about the probability of failing name review. The empirical analysis in the paper confirms this prediction.
In the following section the genesis of the inadvertent policy experiment analyzed in this paper is discussed. Section 3 provides a model and Section 4 a discussion of how the policy experiment can be exploited empirically. Then Section 5 introduces the data. Section 6 sets out the empirical results. In Section 7 I discuss the implications of my findings and the potential for further work.

2 An Inadvertent Policy Experiment

This section reviews how European Enlargement (EU enlargement) in 2004 and the regulation of invented names by the European Medicines Agency (EMA) created the policy experiment exploited in this paper. In this section I argue that regulation of invented names became significantly stricter, in the sense that the probability of clearing a given name with the EMA became less likely, as a result of EU enlargement. First, I discuss EU enlargement, then invented name review and finally the strategies firms adopt in the face of invented name review.

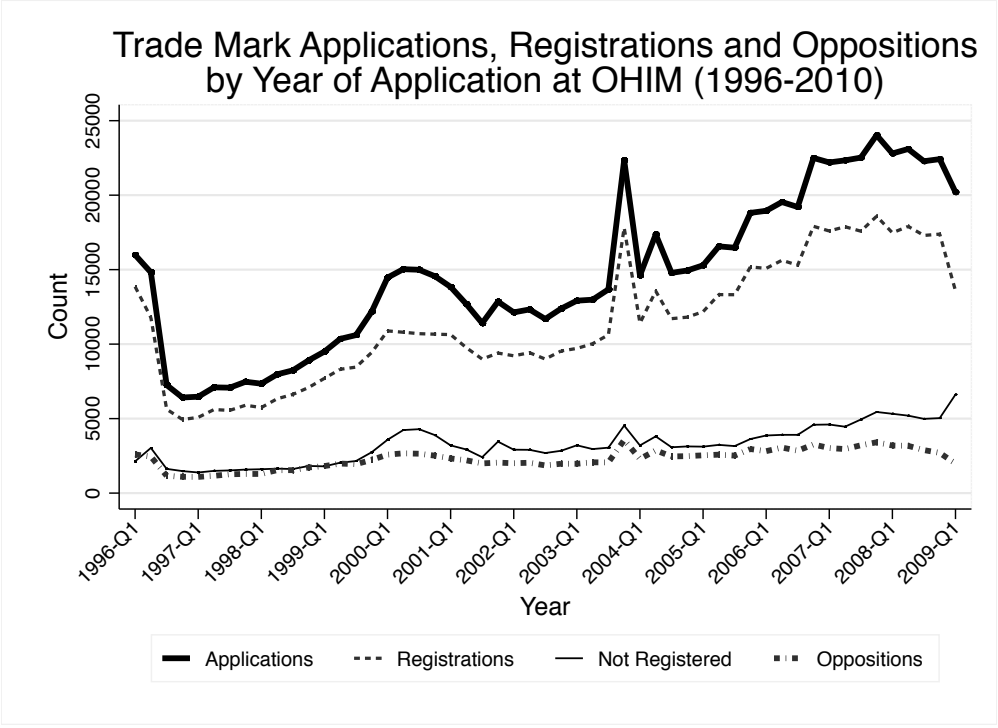

Figure 1: Demand for the Community Trade Mark 1996-2009
Note: This figure is based on register data provided by OHIM. The last five quarters of the graph are affected by a grant lag as discussed in the Appendix to Kur et al. (2011). The graph presents the count of applications, registrations and oppositions based on the date of the trade mark application.

On the 1.5.2004 Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia joined the EU and thereby OHIM and EMA. In this study it is assumed that this event was exogenous to the workings of the trade mark system, in the sense that there was no feedback from firms' application strategies to EU enlargement. This assumption seems defensible - it is hard to conceive of a way in which the trade mark application strategies of any firm should have driven the process of EU enlargement.
Enlargement in 2004 required two treaties to be signed and ratified: the Treaty of Nice which amended the institutional structure of the European Union and the Treaty of Accession which formalized accession by the new member states. Although the Treaty of Nice was signed in February of 2001 some uncertainty remained as the treaty was initially rejected by voters in Ireland in June of 2001. However, over time this uncertainty dissipated as it became clear that the Irish government was committed to securing an acceptance of the Treaty of Nice.
The countries acceding to the European Union in 2004 accepted that trade marks registered at OHIM would automatically be extended to their territories after accession. No further examination of these marks by trade mark offices of the acceding countries would take place. This accounts for the spike in trade mark applications at OHIM just before accession in 2004 that is visible in Figure 1.

The review of invented names for ethical drugs in Europe began in 1999 when EMA set up the Invented Name Review Group (NRG). This happened in response to papers in medical journals (Costable Jr and McKinley, 1996; Raffalli et al., 1997) which reported medication errors resulting from confusion caused by similar names given to ethical drugs, e.g. Losec[10] and Lasix[11]. Further systematic evidence of medication errors resulting from name confusion was provided in a report by the Institute of Medicine (Kohn et al., 2000).
In the EU approval for new drugs and their names can be obtained through several alternative procedures: a national procedure, a decentralized procedure or a mutual recognition procedure. These procedures involve national regulators. Alternatively, EMA offers a centralized procedure of drug review for the whole EU. For certain kinds of drugs only the centralized procedure is available.[12] If there is any danger that consumers in any country within the European Union might confuse a name proposed for a new medicine with that of an existing medicine the name is not approved. Proposed names also should not mis-

[10] A proton pump inhibitor used to prevent gastric ulcers.

[11] A diuretic used to treat high blood pressure.

[12] These are: human medicines for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases; veterinary medicines for use as growth or yield enhancers; medicines derived from biotechnology processes, such as genetic engineering; advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines; officially designated 'orphan medicines'.

lead consumers regarding therapeutic effects or the composition of the product. EMA approve all medicines in the EU that choose the centralized procedure. The NRG liaises with the National Competent Authorities (i.e. national human medicines regulators) to determine whether a given proposal is acceptable or not. EU enlargement increased the number of these authorities by ten. As each authority can effectively block a proposed name throughout the EU under the centralized procedure, enlargement reduced the probability that a given name would be approved by the NRG, making invented name review much stricter. Also, firms that adopted the alternative name regulation procedures noted above, would have faced a higher probability of failing invented name review, unless they were willing to avoid the new member states' markets altogether.

Producers of ethical drugs respond to the possibility that names may be rejected during invented name review by filing more than one candidate name per new product (Kenagy and Stein, 2001; Wick, 2011; Lallemand, 2011). The costs of developing a suite of candidate names is high for ethical drugs: Kenagy and Stein (2001) and several online sources[13] indicate that identification of three or four new names for pharmaceutical products can cost anything between US $100,000 and US $700,000 and in some cases substantially more. Wick (2011) cites a maximum figure of US $ 2.25 million.[14] The high costs of creating pharmaceutical names results from the particular importance of the brand name for pharmaceutical products and the additional tests performed to identify pharmaceutical brand names. Pharmaceutical names are tested with the help of panels of several hundred paid health care professionals and include prescription simulation exercises, tests of name similarity, tests of implied claims conveyed by a name, tests of visual and verbal similarity and finally linguistic analysis to determine how the brand is received by people with different cultural backgrounds (Ellerin and Breen, 2006; Wick, 2011).[15]
More generally the marketing literature emphasizes the importance of the brand name for success of any new product introduction and the complexity of brand name creation (Bao et al., 2008). This literature also provides some evidence that brand name creation is significantly cheaper for manufacturing goods than for ethical drugs: Kohli and LaBahn (1997) surveyed brand managers at 101 US corporations and found that brand name creation cost US $7600[16] on average. The main reason for the much higher costs in pharmaceuticals are that ethical

[13] Similar costs are independently reported by USA Today, Marketplace and English Mojo.
[14] Compare this with costs of US $ 1 million for the redesign of the pepsi logo reported by ADAGE.COM, the costs of US $ 650,000 for creation of the logo of the 2012 Olympic Games in London and the US $ 1,8 million for the redesign of the BBC logo in 1997 reported by Stocklogos or the recent rebranding of Oxfam for £550,000 reported by Designweek.
[15] The Interbrand report can be found at INTERBRAND.
[16] US $8485 - US $ 9400 in 2004, depending on the price deflator used. The higher sum is

drugs are marketed globally and that name confusion has much greater costs than in other areas, leading to stricter standards and more careful scrutiny of names (Wick, 2011).
Below I analyze the effects of EU enlargement on the number of invented names that producers of ethical drugs submitted per product. First, I develop a model of applications for invented names and second I test its predictions using european trade mark data.

3 A Model

This section sets out the main findings from a model provided in the appendix. The model captures the interaction between trade mark applicants and the medical regulator[17]. The model serves several purposes. First, it identifies a condition under which a lower probability of passing invented name review increases the number of invented names submitted to the NRG for each product. Second, it provides a further testable predictions. Third, the model determines variables that should be included as covariates in the econometric models used to test these hypotheses. Fourth, the model provides a basis for the calculation of the proportion of trade marks that are registered by applicant firms to ensure that they obtain at least one mark per product. This number is needed to analyze the costs of cluttering for pharmaceutical firms.
The model builds on the sequential nature of decisions in the process of ethical drug development: Adams and Brantner (2006) show that the process of obtaining regulatory approval for an ethical drug took between 5 and 8 years in the period analyzed in this paper. Meanwhile De Benedetti et al. (2006) indicate that firms seek to obtain regulatory clearance for trade marks three to four years before a drug is brought to market. Kenagy and Stein (2001) state that firms begin developing brand names after animal testing and concurrently with human trials. For each generation of potential drugs firms will make the following decisions in sequence:

Stage 1: Firms determine the probability p with which they obtain a new medicine by investing in R&D. I assume that the R&D cost function $\gamma(p)$ is continuous and increasing in p and $\gamma(0) = 0$ while $\gamma(1) = \infty$.

Stage 2: Firms choose the number of trade marks (M) to register with the

based on the Consumer Price Index for All Urban Consumers: Services (CUSR0000SAS), the lower on the Producer Price Index: Intermediate Materials: Supplies & Components (PPIITM) as provided by the Federal Reserve Bank of St. Louis.

[17] In this model the medical regulator is not optimizing an objective function. The argument of the paper is that stricter review of names for ethical drugs is having effects on the trade mark register which the regulator is not taking into account. As the medical regulator is not charged with management of the trade mark register, this is not surprising.

trade mark office and to refer to the medical regulator, given the probability μ that the medical regulator will reject a mark.[18]. Costs of registration and referral are C per mark.

Firms determine their R&D investments at Stage 1 taking into account the expected probability of rejection of each proposed name: μ. To keep the model simple I assume that firms will obtain high profits ($\bar{\pi}$) if they innovate and if they obtain regulatory clearance for at least one mark. If firms fail to obtain regulatory clearance for a trade mark, their profits will be π, where $\bar{\pi} > \pi$. This captures the costs of delay faced by firms that do not at first obtain a trade mark which the medical regulator has cleared. Finally, firms which fail to innovate will obtain profits $\underline{\pi}$, where $\pi > \underline{\pi}$.

The model is solved by backward induction. To derive the firms' value functions note that the probability that at least one submitted mark is not rejected is $(1 - \mu^M)$. Firms' Stage 2 value function is:

$$V_M = (1 - \mu^M)\bar{\pi} + \mu^M \pi - CM \quad . \tag{1}$$

The optimal number of trade marks to register ($\hat{M}$) is implicitly defined by:

$$\mu^{\hat{M}}(\bar{\pi} - \pi)\ln\mu - C = 0 \quad . \tag{2}$$

Since R&D decisions are made before firms determine how many names to apply for per drug, it is possible for the regulatory regime applying to medical names to change in the period between both decisions. If this happens, firms can adjust to the new regime only by choosing a number of trade marks M at Stage 2 that differs from the number anticipated when the firms made their R&D decisions. In the appendix I show that the following proposition can be derived:

Proposition 1

If the probability of rejection increases from μ_l to μ', then firms apply for more names per drug as long as $\mu' < \bar{\mu} \equiv e^{-\frac{C \cdot e}{\bar{\pi} - \pi}}$.

$\bar{\mu}$ depends on the ratio of the costs of registering a trade mark and obtaining regulatory approval (C) to the foregone profits if no mark is approved by the medical regulator ($\bar{\pi} - \pi$). In the pharmaceuticals industry it is safe to assume that this ratio is quite low according to the interviews I undertook with representatives of several firms. Lallemand (2011) indicates that approximately half of all applications at the NRG fail, while De Benedetti et al. (2006) indicate that approximately 40% fail. If we assume that 50% fail, this would imply that lost profits should be at least four times larger than costs of registration and ex-

[18] Implicitly I assume that the trade mark office registers all marks with probability one. This simplifying assumption has no substantive impact on the results of the model.

amination by the NRG. Lallemand (2011) notes that costs of failing to secure approval by the NRG for at least one trade mark per medicine can reach "hundreds of millions of dollars". Registering a set of trade marks with OHIM and referring them to the NRG costs substantially less than this.
In the appendix (Proposition 2, Section 8.1) it is shown that a lower probability of passing name review reduces firms' expected profits from R&D, which reduces R&D investments and will reduce the observed number of name applications per product. The observed number of name applications per product in pharmaceutical Nice classes ($\bar{n}$) can be expressed as follows:

$$\bar{n} \equiv \frac{O \cdot m + N \cdot M}{O + N} \quad , \tag{3}$$

where O is the number of trade mark application events observed in pharmaceutical Nice classes that do not relate to products vetted by the NRG, N is the number of trade mark application events affected by name review. If there is no name review firms apply for m marks per application event, while firms facing name review choose to make M applications per event. In the data presented below only $\bar{n}$ and m are directly observable. Note that $\bar{n}$ is increasing in M and N.
Overall the model leads to two hypotheses:

H1: Firms who have committed R&D to drug research and are affected by an unanticipated increase in the probability that invented names will fail at the NRG will increase the number of names (M) they submit to the NRG. This increases $\bar{n}$.

H2: Once the probability that invented names fail at the NRG (μ) increases, firms R&D investments on new drugs fall and so does the number of trade mark application events N. This reduces $\bar{n}$ two years after EU enlargement.

These hypotheses are tested using two complementary empirical approaches which are presented next.

4 Identifying The Causal Effect of EU Enlargement

In this section I discuss two complementary empirical approaches to the estimation of causal effects in the context of a policy shock such as EU enlargement.
EU enlargement reduced the probability that the NRG accepted invented names submitted after 2004. Invented name review only affects producers of ethical drugs. Therefore EU enlargement should not have affected the number of simultaneous trade mark applications made by firms not producing ethical drugs. The most widely used estimator in such a setting is the Difference-in-Differences (DID) estimator. It provides a comparison of the change in the number of simul-

taneous applications in pharmaceutical Nice classes to the change in the number of simultaneous applications in other Nice classes in 2004. This comparison of changes means that the estimator nets out any preexisting, constant differences in the pre-enlargement propensity to apply simultaneously for trade marks. This property of the estimator is useful, as any unobservable time-constant differences between trade mark applicants do not bias the estimated coefficients.

Below I distinguish between four groups of trade mark applications, one of these being applications made in pharmaceutical Nice classes.[19] Additionally, I take into account that firms may have anticipated EU enlargement. I control not only for the effect of EU enlargement after 2004 but also in the 11 quarters before EU enlargement.

In the notation used by Imbens and Wooldridge (2009) the model estimated is:

$$A_i = \alpha + \beta T_i + \sum_{g=1}^{4} \gamma_g \cdot 1[G_i = g] + \sum_{g=1}^{3} \tau_g \cdot 1[G_i = g, T_i = 1] + \boldsymbol{X'\theta} + \epsilon_i \ , \quad (4)$$

where A_i denotes the number of simultaneous applications, T_i is an indicator variable set to one for all quarters after EU enlargement took place, $G_i = g$ is an indicator variable for each group of trade marks I distinguish and $\boldsymbol{X}$ is a vector of covariates. The main coefficients of interest are the τ_g coefficients on the interaction of the time and group indicator. In particular, I am interested in the interaction coefficient for pharmaceuticals firms (τ_p) as this identifies the causal effect of EU enlargement on the number of simultaneous trade mark applications, if the DID estimator can be relied upon.

The DID estimator is unbiased given two important assumptions. The first assumption is the common trends assumption: only if the number of simultaneous applications chosen by pharmaceuticals and other firms follows the same trends before and after the shock of EU enlargement will the estimator reliably estimate the causal effect of the policy shock (Abadie, 2005; Imbens and Wooldridge, 2009). The graphical evidence provided in Figure 2 above suggests that the trends in simultaneous applications after 2004 were the same for pharmaceutical and other firms. Between 1996 and 2000 and 2001 and 2004 trends also seem comparable. Between 2000 and 2001 there is a clear increase in the level of simultaneous applications by pharmaceutical firms relative to other applicants. So the common trends assumption does not hold for the entire sample period. I deal with this below by including a dummy variable for the period between the fourth quarter of 1999 and the fourth quarter of 2000 in my regressions.

The second important assumption is that the groups being compared with the estimator are similar in the covariate dimensions. Imbens and Wooldridge (2009)

[19] Comparisons between the other three groups provide additional tests of the model, as is discussed below.

note that the average treatment effects estimated by regression methods, such as DID, become highly sensitive to functional form, if this assumption fails. As illustrated in Section 5 below the means of the covariates for observations in the pharmaceutical (treatment) and artifacts (control) groups in the data used here are not balanced, i.e. the groups are dissimilar.

To overcome this problem I complement the results from the DID estimator with results obtained with the nearest neighbour matching estimator introduced by Abadie et al. (2004). This estimator is more efficient than the more widely used propensity score matching estimator (Abadie et al., 2004; Imbens and Wooldridge, 2009; Abadie and Imbens, 2011). The estimator combines nearest neighbour matching, which compares each treated observation with one or more similar observations from the control sample, and regression, which reduces remaining biases due to covariate imbalances (Imbens and Wooldridge, 2009; Abadie and Imbens, 2011). The estimator only provides estimates of the treatment effect, which is comparable to the interaction of the pharmaceuticals dummy with the enlargement dummy in the DID framework (τ_g).

The nearest neighbour matching estimator also relies on two important conditions: unconfoundedness and overlap. Together these conditions imply that a causal effect can be ascribed to the estimates obtained with this estimator. In the literature on potential outcomes this is referred to as strong ignorability (Imbens and Wooldridge, 2009; Imbens and Rubin, 2011; Ho and Rubin, 2011).

While the DID estimator is unaffected by sample selection if common trends obtain, the same is not true of the nearest neighbour matching estimator. This estimator requires that assignment to the group of treated observations is random, conditional on observable determinants of assignment and of potential outcomes (Imbens and Wooldridge, 2009). In the context of this paper the decision to become or remain a manufacturer of ethical drugs is referred to as assignment: with this decision firms assign themselves to the group affected by the policy change in invented name review. The most important result of the potential outcomes framework shows that a causal interpretation of a policy experiment is possible in the absence of random assignment, if assignment probabilities do not depend on the potential outcomes or their determinants. Assignment is then called unconfounded.

The theoretical model analyzed in Section 3 shows that the number of trade marks a firm applies for per product depends on the probability of passing invented name review (μ), as well as the costs of registering trade marks and of referring them to invented name review and the foregone profits if no trade mark is successfully registered. These variables are not all observable. They would create sample selection problems if they differ systematically for firms affected by invented name review and for firms not affected by it. Costs of registration and referral of trade marks vary only in a few discrete steps in the period of ob-

servation, so they are not candidates for sample selection problems. However, foregone profits will be very heterogeneous across firms and markets. If there are unobserved determinants of foregone profits, that also systematically affect whether firms face invented name review, then a causal effect of EU enlargement cannot be identified without additional assumptions.

The high R&D costs of ethical drug development are an important determinant of foregone profits. Manufacturers of ethical drugs screen out all products which do not promise a sufficiently high return to cover these sunk costs. Thus it is important to control for differences in R&D intensity when studying the effects of tighter invented name review after 2004. This is possible and I comment on it below. Other determinants of foregone profits are unlikely to affect both selection into manufacturing of ethical drugs and the number of trade marks to apply for as both decisions are separated by a long period of time.

Note also that the decision to become or remain active as a manufacturer of ethical drugs is taken at least five years before a drug is finally brought to market. Often the period between commencement of R&D and market entry will be much longer than this (Adams and Brantner, 2006). The decision is also taken at a time when the the value of a compound that will become a drug is highly uncertain. Once it is clear that a candidate compound can be marketed as a drug the firm decides to apply for trade marks. At this stage several years will have passed and many other determinants of foregone profits will have changed relative to the time at which the R&D decision is taken. This also reduces the likelihood of a serious sample selection issue arising from unobserved determinants of foregone profits.

Overall this discussion suggests that assuming selection into treatment is unconfounded is not unreasonable. Then, the next question is whether the overlap assumption is satisfied: this is the case, if there are sufficient numbers of firms with similar characteristics in the treatment and control groups. This condition is important to ensure that each firm in the group of ethical drug manufacturers can be compared with a firm that is very similar to it in all dimensions apart from treatment. This allows the researcher to identify the effect of treatment most precisely. Given both the unconfoundedness and the overlap conditions are satisfied, strong ingnorability obtains (Imbens and Wooldridge, 2009). This implies that a causal effect can be ascribed to the estimates presented below. I discuss overlap further once the characteristics of the sample are presented.

The nearest neighbour matching estimator can be specified in a number of different ways to estimate slightly different treatment effects. The literature on program evaluation (Imbens and Wooldridge, 2009) distinguishes between population average treatment effects (PATE) and population average treatment effects on the treated (PATT). In the context of this study the PATE corresponds to the effect of exposing the entire population of trade mark applicants to a drop in

the probability of passing invented name review equivalent to that experienced by pharmaceutical firms in 2004. The PATT is defined as the effect of tougher invented name review for pharmaceutical trade mark applicants only.
EU enlargement increased regulatory uncertainty facing pharmaceutical applicants in what was already a more onerous trade mark application process than that faced by other trade mark applicants. Therefore, the PATE is somewhat hard to grasp in the context of this study. It is hard to envisage a policy change affecting all trade mark applicants that is exactly as strong as the difference between the regulatory regimes facing pharmaceutical trade mark applicants before and after 2004. In contrast to the PATE the PATT captures the effect on pharmaceutical trade mark applicants of the shock of EU enlargement. Below I focus mainly on the more clearly defined PATT.

5 Data and Descriptive Analysis

This section presents and discusses the data used in this study. The data are obtained from register data supplied by the european trade mark office (OHIM). Figure 2 below provides a descriptive impression of the intensity and development of simultaneous applications for the period between 1996 and 2010. The figure shows that the average level of simultaneous applications in Nice classes related mainly to pharmaceutical products becomes significantly greater than in other Nice classes in the period of the new economy around the year 2000. The figure also shows that just before European Enlargement in 2004 the number of simultaneous applications in all groups of Nice classes increases. This corresponds to the spike in applications apparent in Figure 1.
Overall Figure 2 suggests that pharmaceutical firms may have anticipated the effects of European Enlargement in the period 2001 to 2004 with the strongest differences between pharmaceutical applicants and other applicants in this period arising in 2002. The figure also suggests that after 2008 the difference between simultaneous applications by pharmaceutical firms and some of the other firm categories decreased slightly. The hypotheses set out in Section 3 suggest just such a pattern would emerge. The econometric analysis presented in the next Section will show whether the relative changes in simultaneous applications are statistically significant and economically important.
Next I turn to a discussion of how the four groups of applications set out in Figure 2 are identified. After that I discuss and analyze the variables used in the econometric analysis of the following section.

Defining the treatment group Trade marks can be registered in 45 different classes (Nice classes) covering the spectrum of goods and services. Trade marks

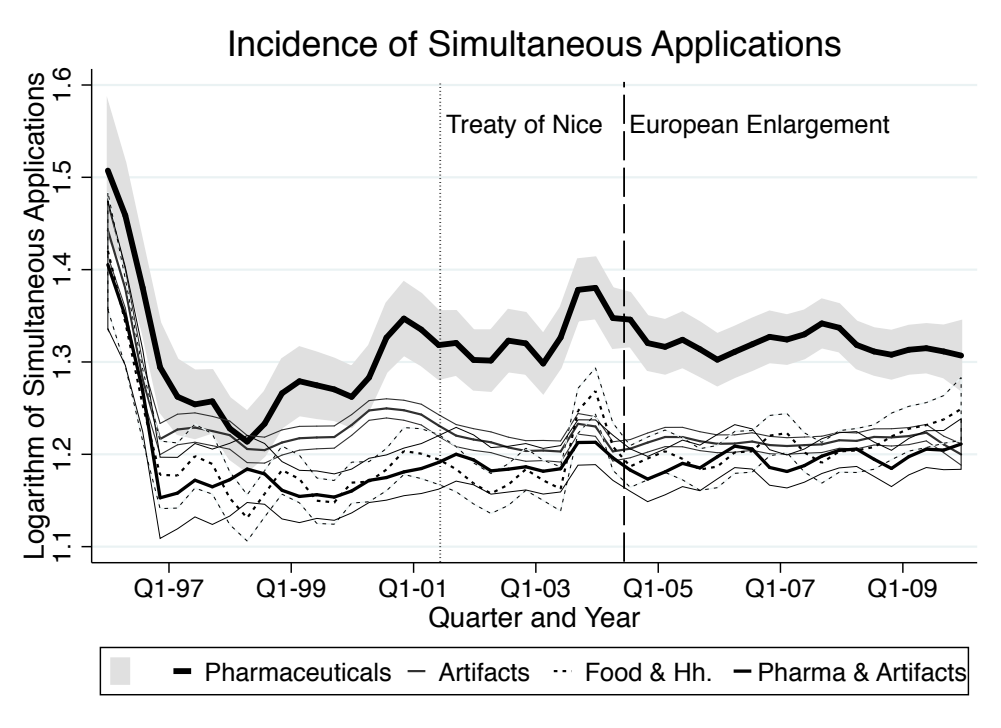

Figure 2: Simultaneous Applications by Type of Trade Mark

Note: This figure is based on register data provided by OHIM. It contains a plot of the average size of simultaneous application events in four kinds of trade mark applications. These are: Trade marks registered mainly for pharmaceutical products, trade marks registered for artifacts, trade marks registered for artifacts and pharmaceutical products and trade marks registered for food and household goods. A more precise definition of these four kinds of registrations is provided below. The vertical dashed line marks the date of European Enlargement and the vertical dotted line marks the Treaty of Nice.

are frequently registered in multiple Nice classes. Pharmaceutical products are registered primarily in Nice class 5.[20]

I do not have data linking trade mark applications at OHIM to review by the NRG. Instead, I study differences between trade marks applied for in Nice classes in which pharmaceutical products are frequently registered and trade marks registered in other classes. One consequence of this is that there will be trade marks connected to medical products that are not subject to review by the NRG in the group of pharmaceutical applications. This leads to the definition of the observed average number of simultaneous applications $(\bar{n})$ in Equation (3). To deal with trade marks registered in multiple Nice classes I divide the set of trade mark applications into four groups: Pharmaceuticals, Artifacts, Food &

[20] The class covers the following types of products: Pharmaceutical, veterinary and sanitary preparations; dietetic substances adapted for medical use, food for babies; plasters, materials for dressings; material for stopping teeth, dental wax; disinfectants; preparations for destroying vermin; fungicides, herbicides.

Household and Pharmaceuticals & Artifacts. This is done in a two step process: First, I identify all Nice classes frequently used in conjunction Nice class 5 on all trade mark applications submitted to OHIM. These classes I refer to as the pharmaceutical Nice classes in this study. Similarly, I identified all those classes very rarely cited in conjunction with Nice class 5 and called these the Artifact Nice classes. In the second step I divided all trade mark applications into four distinct groups, depending on whether they cite one, both or neither of these two groups of Nice classes.

Table 1: Distribution of Trade Mark Applications

	Type of Industry		
	Artifacts	**Food & Household**	**Pharmaceuticals**
Nice Classes	6, 7, 9, 12, 16, 18 19, 25, 28, 33, 35, 36, 37, 38, 39, 41, 43 ,45	11, 20, 21, 29, 30, 31, 32, 42	1, 3, 5, 10, 13, 44
Description	Metals, Machines, Scientific Apparatus, Vehicles, Leather, Building, Clothing, Games, ...	Lighting, Furniture, Household utensils Food, Coffee, Produce, Beer,	Chemicals, Laundry, Pharmaceuticals, Medical Apparatus, Firearms, Medical Services
N	395,991	71,226	76,201

Any trade mark application citing a Nice class contained in the set of pharmaceutical Nice classes and not citing a Nice class contained in the set of artifacts Nice classes is a Pharmaceutical application. Likewise, any applications citing a Nice class contained in the set of artifacts Nice classes but not citing a Nice class contained in the set of pharmaceuticals Nice classes is an Artifacts application. If neither Nice classes falling into the set of pharmaceutical or artifacts Nice classes are cited the application is classified as falling into the Food & Household category. If both sets of Nice classes are cited the application is classified as falling into Pharmaceuticals & Artifacts. Table 1 sets out which Nice classes fall into the first three of these groups. It also provides some information on the types of products covered by the classes and on the number of applications in each category. Pharmaceuticals & Artifacts, contains 54,806 observations.

The dependent variable The dependent variable is a count of the number of trade mark applications made by one firm on one day using the same set of Nice classes. Just to count multiple applications is misleading, if firms sometimes simultaneously register both a word mark, a figure and possibly a smell or a shape to protect their product. Therefore, I distinguish between these different types of applications and only count those cases in which a firm simultaneously

applies for more than one of each type of trade mark. Seven types of trade mark are distinguished.[21] I treat each such event as an *application event* intended to produce at least one trade mark for a new product.

Simultaneous applications may also reflect brand extension efforts. Firms may seek to apply simultaneously for several variants of existing marks or for a number of variants of a new brand name. This can add measurement error to the dependent variable used in this study, if I do not capture this using covariates such as the new combination dummy described below. In linear models such as the DID model, measurement error affects the reliability of inference only in small samples unless the measurement error component of the dependent variable is correlated with the covariates of the model (Wooldridge, 2002). I discuss this problem in more detail in the context of the results.

Between 1.1.1997 and 1.1.2010 there are 597,450 application events in the dataset for which I have sufficient information to include them in the analysis. Of these 11.75% (70,182) are events in which a firm applied for more than one trade mark of one type simultaneously. If I apply the concept of surplus marks as outlined above, then these simultaneous applications added 124,751 surplus trade marks to the register at OHIM between 1997 and 2009. This represents 15.44% of applications in this period.

Surplus CTMs that are not used could be removed from the register after 5 years, due to the use requirement. Removal requires action by a third party seeking a cancellation. In practice cancellations are very rare, making up only 0.44% of all registrations before 2006. Therefore, surplus trade marks are likely to be removed from the register only 10 years after filing, when they are not renewed.

Covariates To capture differences amongst firms and changes in firm strategy a number of covariates are derived from the administrative data used here.

Three covariates capture aspects of firm strategy:

- *Past applications:* To capture changes in firm strategy I construct a measure of the average number of simultaneous applications in each firm's previous applications. This is a continuous variable.
- *New combination dummy:* Another measure of a change in strategy is a dummy variable that is set to one if the combination of Nice classes the firm is citing on its applications is new to that firm.
- *Breadth:* To capture the breadth of a firm's activities I count the total number of distinct Nice classes which each firm is active in.

Three covariates measure firm characteristics for a subset of firms:

[21] There are word marks, figurative marks, three dimensional marks, colour marks, olfactory marks, holograms and a residual category.

- *Age:* To measure the age of the applying firm I extract the age of the oldest trade mark in the portfolio of each applicant. This age measure is available where firms have cited previously existing trade marks (seniorities) in their applications for an OHIM trade mark. The variable is continuous.
- *Seniorities:* This variable contains a count of trade marks with seniorities[22] which the firm applies for over the entire sample period. This provides an approximation to the size of the firm before 1996, if the firm cites previously existing trade marks in its applications for OHIM trade marks. The variable is a count variable.
- *No seniorities dummy:* This dummy variable is set to one for firms that do not cite a seniority in their trade mark application.

Two covariates capture differences between industries:

- *Opposition rate:* This variable measures the proportion of applications opposed that are applying to a particular combination of Nice classes. This variable is continuous.
- *Registration rate:* This variable measures the proportion of applications registered that are applying to a particular combination of Nice classes. This variable is continuous.

The remaining covariates capture country, industry or time fixed effects:

- *Country:* For each firm the country of origin is recorded. This information is included in the regressions as significant national differences between the trade marking strategies of firms can be detected. These effects are assumed to remain fixed over time.
- *Nice dummies:* For each application the combination of Nice classes used is employed to capture industry specific differences in trade marking behavior that are fixed over time.
- *Quarter:* In aggregate time series of trade mark applications significant differences between the application rates in different quarters can be observed. Therefore I include dummy variables for quarters in the regressions below.
- *Year:* Year dummies are included in most regressions below to capture effects of the business cycle or other shocks that are specific to individual years and affect all applicants equally.

Descriptive Statistics Next I provide descriptive statistics. Table 2 provides the mean for the full sample and an outlier corrected sample used to test the

[22] A seniority claim merges a CTM with an earlier identical national mark. This means the owner can continue to enjoy the rights from the national mark, even if that lapses, as long as the CTM is registered. For the purposes of the analysis here a seniority claim indicates that prior to 1996 the firm had national marks.

robustness of the Difference-in-Differences estimator.[23]
It may be interesting to note that the median number of Nice classes that firms apply for is 3 because OHIM charge the same amount for application and registration regardless of whether the applicant chooses to register in one, two or three classes. Costs for any additional classes increase linearly.

Table 2: Descriptive Statistics

Variable	**Mean**	(Outlier corr.)	**S.D.**	**Median**	**Min.**	**Max.**
Simultaneous Applications	1.200	(1.194)	1.317	1	1	634
Anticipation dummy	0.197	(0.197)	-	0	0	1
Expansion dummy	0.549	(0.549)	-	1	0	1
Pharmaceutical dummy	0.127	(0.127)	-	0	0	1
Food & Household dummy	0.092	(0.092)	-	0	0	1
Pharmaceuticals & Artifacts dummy	0.119	(0.119)	-	0	0	1
Breadth	2.738	(2.738)	2.400	3	0	45
Opposition rate	0.141	(0.141)	0.134	0.142	0	1
Registration rate	0.704	(0.704)	0.224	0.771	0	0.98
Past applications	0.782	(0.780)	1.115	1	0	329
New combination dummy	0.645	(0.645)	0.479	1	0	1
Seniorities	2.980	(2.978)	16.945	0	0	349
Age (days)	326.838	(326.806)	2353.043	0	0	66,875
No seniorities dummy	0.994	(0.994)	-	1	0	1

Based on 597,450 (597,339) observations of application events.

In addition to the usual statistics I also report the normalized differences of the covariates between treated observations and the controls. As noted by Imbens and Wooldridge (2009) and Abadie and Imbens (2011) this statistic is informative about the extent to which the use of linear regression analysis can be relied upon without recourse to strong assumptions about functional form. Imbens and Wooldridge (2009) and Imbens and Rubin (2011) suggest that the normalized differences should not be greater than a quarter.
Table 3 shows that this condition is not met for several of the covariates reported here, the statistic is set in **boldface** for these. This indicates that the nearest neighbour matching estimator of Abadie et al. (2004) rather than the Difference-in-Differences estimator be used. The latter is likely to be unreliable in predicting effects of treatment in the treated sample as firms in both samples are on average too different for those covariates where the normalized differences are high.

[23] Below the DID model is estimated once with a sample corrected for outliers to ensure that application events with large numbers of simultaneous applications are not distorting the estimated coefficients. These outliers are likely to arise when firms decide to apply for large parts of their existing portfolios at OHIM on the same day, for instance when first beginning to use the CTM system.

Table 3: Covariate Balance Before EU Enlargement

Variable	**Treated** Pharmaceuticals	(sd)	**Controls** Artifacts	(sd)	**Norm. Diff.**
Breadth	1.74	1.00	2.68	1.73	**-0.489**
Opposition rate	0.20	0.09	0.14	0.08	**0.776**
Registration rate	0.78	0.14	0.71	0.21	**0.395**
Past applications	1.00	1.01	0.74	2.48	0.195
New combination dummy	0.50	0.50	0.69	0.46	**-0.377**
Seniorities	8.56	31.46	2.20	13.64	**0.275**
Age (days)	543.99	2507.11	346.78	1801.60	0.072
No seniorities dummy	0.93	0.26	0.95	0.23	-0.075

Normalized differences calculated using PSMATCH2 (Leuven and Sianesi, 2003) in STATA.

6 Empirical Models and Results

This section provides results from DID regressions based on Equation (4) as well as results obtained by applying the nearest neighbour matching estimator introduced by Abadie et al. (2004).

First I discuss results from a DID regression. Table 4 sets out results from four specifications: the basic DID specification as set out in equation (4) applied to the full data and applied to an outlier corrected data set, a specification allowing for variation over the quarters of a year and finally another allowing for a time trend. The artifacts category is always the reference category. Imbens and Wooldridge (2009) note that standard errors usually reported may not be reliable for a DID regression. Therefore, I report robust standard errors and cluster at the level of the trade mark applicant to control for correlation of outcomes.

Hypotheses I and II state that the number of trade marks applied for per product in the Pharmaceutical group should first increase and then slightly decrease around the time of EU enlargement. The specifications reported in Table 4 below contain two parameters that test these predictions: the interactions of the pharmaceutical dummy with the anticipation and expansion dummies.

Table 4 shows that in the first three specifications reported there is a clear and significant effect of EU enlargement on the number of simultaneous applications by pharmaceuticals firms. It is also interesting to note that the effect of the anticipation of EU enlargement on simultaneous applications in pharmaceuticals is stronger than the effect of enlargement itself. Finally, it is comforting to observe that the effect of enlargement is stronger in pharmaceuticals than in the two intermediate groups of Food & Household and Pharmaceuticals & Artifacts. The relative size of the anticipation- and enlargement-by-pharmaceuticals interaction effects fit the predictions of Hypotheses I and II very well, if we can expect to see an effect of EU enlargement on simultaneous trade mark applica-

tions before the actual date of EU enlargement. De Benedetti et al. (2006) note that producers of ethical drugs should apply for trade marks for new drugs up to four years before product launch. Then we would expect to see exactly the pattern which the two interaction dummies present. I conclude that Hypotheses I and II are not rejected by specifications 1-3.

Table 4: Results from Difference-in-Differences Models Estimated by OLS

	Base	Outliers	Quarter dummies	Time Trend
Expansion dummy	-0.014	-0.040**	-0.028*	-0.026*
	(0.029)	(0.013)	(0.012)	(0.013)
Pharma dummy	0.004	0.009	0.005	-0.042
	(0.018)	(0.016)	(0.018)	(0.131)
Food & Household	-0.033*	0.016	-0.034*	-0.217*
dummy	(0.015)	(0.016)	(0.015)	(0.091)
Pharma & Artifacts	0.024†	0.018†	0.024†	0.097
dummy	(0.013)	(0.011)	(0.013)	(0.097)
Anticipation ×	0.059***	0.061***	0.058***	0.054**
Pharma	(0.014)	(0.013)	(0.014)	(0.020)
Expansion ×	0.043***	0.043***	0.043***	0.034
Pharma	(0.013)	(0.012)	(0.013)	(0.028)
Expansion ×	0.018*	0.020**	0.018*	-0.017
Food & Household	(0.008)	(0.007)	(0.008)	(0.019)
Expansion ×	0.016*	0.021**	0.016*	0.030
Pharma & Artifact	(0.008)	(0.007)	(0.008)	(0.021)
Past	0.396***	0.178***	0.396***	0.396***
applications	(0.039)	(0.041)	(0.039)	(0.039)
New combination	-0.096**	-0.257***	-0.096**	-0.096**
dummy	(0.032)	(0.032)	(0.032)	(0.032)
Age	-0.000†	-0.000	-0.000*	-0.000*
	(0.000)	(0.000)	(0.000)	(0.000)
No seniorities dummy	-0.139***	-0.078***	-0.138***	-0.138***
	(0.013)	(0.013)	(0.013)	(0.013)
Constant	1.048***	1.273***	1.048***	1.047***
	(0.046)	(0.046)	(0.046)	(0.046)
R-squared	0.220	0.114	0.220	0.220
N	597450	597339	597450	597450

† $p<0.10$, * $p<0.05$, ** $p<0.01$, *** $p<0.001$. Robust standard errors in parentheses, standard errors clustered at firm level. Models include country, year and Nice class dummies and additional covariates.

In the fourth specification the inclusion of the time trend increases the standard errors of the focal effects, rendering the enlargement-by-pharmaceuticals interaction not significant. Note that the coefficient does not decrease much, in-

dicating that the effect is not just an artifact of the omitted time trend. Overall, specification 4 is also commensurate with Hypotheses I and II.

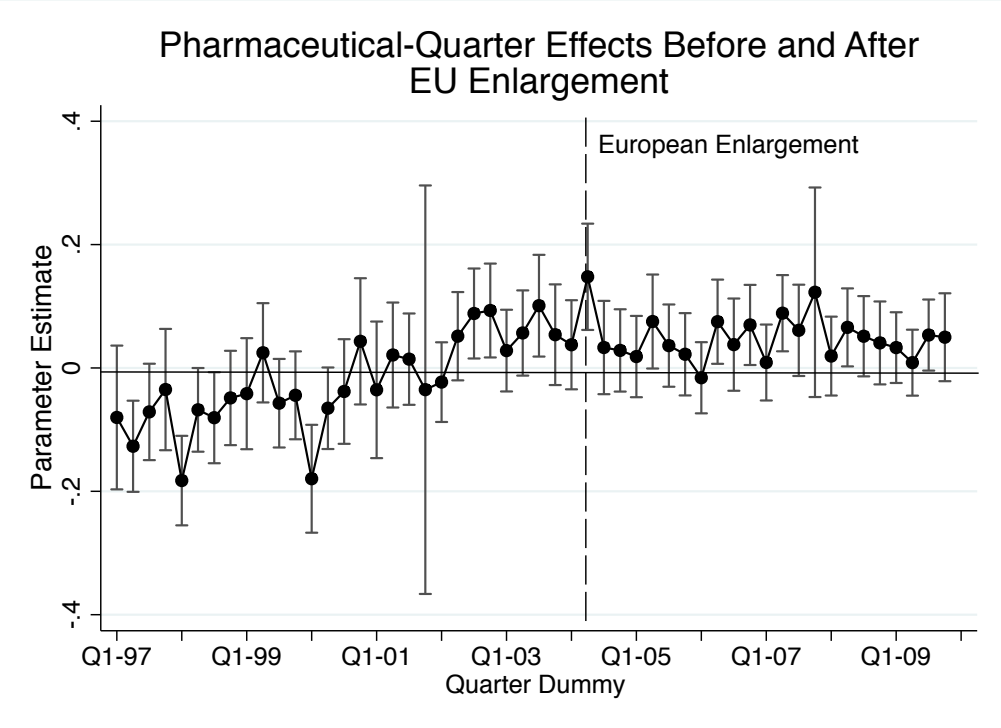

Figure 3: Robustness check - Interacted Quarter Dummies

Note: Estimated impact of European Enlargement on the number of simultaneous trade mark applications in the Pharmaceuticals Nice classes relative to Artifacts Nice classes. Estimates are from a model allowing for effects before and after enlargement. The model is otherwise identical to those presented in Table 4. Vertical lines mark two standard errors. The vertical dashed line marks the date of European Enlargement.

As a final robustness check for the DID estimator I estimate a model allowing for effects of enlargement on simultaneous applications at any time. The results are summarized in Figure 3 as there are too many coefficients to tabulate. The figure suggests that while enlargement had an effect on firms' simultaneous applications this effect was most pronounced in the period before enlargement (2002-2003) and again sometime after enlargement (2006-2007) with the effects before enlargement being somewhat stronger. These results support those found in the time trend specification discussed above.

Prior to enlargement the EU had 15 member states. If I extrapolate the effects of enlargement identified here to the overall effect of invented name review on firms' trade mark applications, then invented name review causes firms to increase their trade mark applications by about 10% ($= 2.5 \times 4.3$) in the long

run.[24] In the sort run the effect can be up to 15%. In 2009 a 10% increase in applications would have corresponded to 1961 surplus applications in pharmaceuticals Nice classes. If invention of each of these marks cost US $25,000, then invented name review led to expenditure of US $49 million on invention of subsequently unused marks in 2009. In Appendix 8.1 I set out an alternative method of deriving the number of surplus pharmaceutical trade marks. This method requires more assumptions but is based on the model set out in Section 3. Based on this I estimate annual costs of inventing surplus marks to have run to US $ 21 million per year between 2001 and 2004.

These results are reliable, if the fact that overlap between the treated group (drug manufacturers) and the control group is not high, does not affect them very much. Additionally, measurement error in the dependent variable might also affect the results reported here. This would only be the case if the proportion of simultaneous applications made for brand extension purposes changed significantly for producers of ethical drugs relative to other firms at the time of EU Enlargement. I currently have no evidence for such a shift in brand extension strategies.

Next, I present results from the nearest neighbour matching estimator that are robust to varying trends in simultaneous applications, but rely on unconfoundedness. To do this I use a 25% random sample of observations drawn from the population of trade mark application events at OHIM. The random sample is used because the matching estimator employed here is computationally very intensive.[25] Below I also report one result from a 50% random sample drawn from the population. As a further robustness a separate 25% random sample was drawn and the results reported here were replicated using this sample. Results were not substantively different from those reported here. Note, that the matching estimator provides only the coefficient of the treatment effect.

In applying the matching estimator the number of matches can be freely chosen. In the results reported below I provide results for 1 and 4 matches as is customary in studies using these estimators. I also report results using a robust estimator for the variance. Thus for each number of matches there are four results depending on whether the PATE or PATT was estimated and depending on whether I adjusted for bias or not.

Table 5 provides results from a matching estimator matching on all covariates *and* the average of each firm's simultaneous applications before 2004. I use the average of a firm's previous simultaneous applications to control for unobserved

[24] The model estimates effects of adding 10 countries to the EU. If effects are linear, then the effect of invented name review for 25 countries is 2.5 times larger.

[25] Estimation on a 25% random sample took two days on a standard 1.7 Ghz Intel Core i5 processor. Estimation on a 50% random sample already took 5 times as long. In results available from the author I show that DiD regression on this 50% random sample yield statistically indistinguishable results from those reported in Table 4.

differences in R&D intensity and firm strategy. This increases the likelihood that the assumption of unconfoundedness is met, as is discussed in Section 4 above. The distance metric used is the diagonal matrix constructed from the inverses of the variances of the covariates (Abadie et al., 2004). Two variables were singled out for exact matching: the quarter and the average of pre 2004 simultaneous trade mark applications. Approximate matching was undertaken on the new nice class combination dummy, the seniorities dummy, the breadth of the application, the opposition rate in the Nice classes of application, the registration rate in these Nice classes, the age of the firm, the country of the applicant and the frequency of trade mark applications before 2004.

Table 5: Results from Matching Estimators

Number of matches	PATT		PATE	
		Robust, Bias adjusted		Robust, Bias adjusted
1	0.1806***	0.1879***	0.0862***	0.0242
	(0.0441)	(0.0429)	(0.0289)	(0.0258)
	53.21%		57.60%	
4	0.1417***	0.1675***	0.1002***	0.0356
	(0.0378)	(0.0352)	(0.0268)	(0.0233)
	45.00%		50.72%	

N=21162

† p<0.10, * p<0.05, ** p<0.01, *** p<0.001. Standard errors in parentheses,

Results of eight separate specifications are reported in Table 5. The table sets out the treatment effect of EU enlargement on the number of simultaneous trade mark applications after 2004, the standard errors of the estimated effects and the proportion of treated cases for which a match was found. Below the table the number of treated observations in the sample is given.

As discussed in Section 4 I am primarily interested in the robust and bias corrected PATT results. These capture the effect of increased toughness of invented name review on producers of ethical drugs. The results demonstrate two things: i) effects of EU enlargement on simultaneous applications are four times as large as those found with the DID estimator and ii) without bias adjustment the effects are also somewhat smaller. This suggests that covariate imbalance is having an attenuating effect on the coefficients here. This fits in with the much smaller estimates of the effect of enlargement on simultaneous applications from the DID estimation where covariate imbalance was even stronger that it would be in the uncorrected matching estimator.

7 Conclusion

This paper exploits a discrete change in the probability that invented names for ethical drugs would be approved by medical regulators that resulted from EU Enlargement in 2004 to estimate the costs of creating surplus invented names in Europe. Using conservative assumptions the lower bound for these costs is estimated to lie in the range between US $21 million and US $49 million per year. As noted by Wick (2011) a significant part of the costs of inventing names for ethical drugs accrues to vetting these names to prevent confusion in different languages. Unused marks languishing on trade mark registers heighten the probability of confusion and prolong the search for suitable new marks. These costs are cumulative, as more unused marks accumulate firms must apply for more marks simultaneously to insure against the possibility of obtaining no marks at all.

While manufacturers of ethical drugs will always seek to insure against failure to obtain a name acceptable to medical regulators and trade mark offices, the extent to which surplus marks clutter trade mark registers could be reduced, if medical regulators and trade mark offices cooperated effectively. Currently there is little evidence in Europe of any cooperation between the medical regulators and the trade mark offices. Meanwhile the FDA has attempted to develop a more effective name review process in a pilot program that received only one application from industry.

If the costs of independent name review identified in the current paper are substantiated by further study, then this suggests that it is worth while persevering in the effort to find ways to remove unneeded pharmaceutical marks from trade mark registers swiftly. Most likely this would require only marginal changes to the implementation of the use requirement for such marks. Clearly invented names rejected by the medical regulator cannot be used for medicines and in most cases producers of ethical drugs will therefore be willing to relinquish the corresponding trade marks. Also the sharing of information amongst producers of ethical drugs about names that failed to pass scrutiny are likely to reduce costs of inventing new names for drugs.

More generally, the results reported in this study indicate that trade mark registers are not always immune against congestion effects. In an early landmark study on the law and economics of trade marks Landes and Posner (1987) argue that the space of names from which firms select marks is so vast relative to demand, that congestion is ruled out. While it may be retorted that the case of pharmaceutical trade marks is very special, in that it involves a second regulatory agency in trade mark review, this is probably an unduly narrow view. von Graevenitz et al. (2012) argue that every firm that is internationally active faces multiple trade mark offices as soon as it desires to obtain a single mark that can

be used world wide. The more offices the firm deals with, the tougher name review becomes. This suggests that the effects identified by this study should also be identifiable for firms that grow large enough to enter foreign markets. In future work I intend to investigate whether firms that are active in multiple jurisdictions are prone to creating unused marks as well.

References

ABADIE, A. (2005): "Semiparametric difference-in-differences estimators," *Review of Economic Studies*, 72, 1–19.

ABADIE, A., D. DRUKKER, J. HERR, AND G. IMBENS (2004): "Implementing matching estimators for average treatment effects in Stata," *Stata journal*, 4, 290–311.

ABADIE, A. AND G. IMBENS (2011): "Bias-corrected matching estimators for average treatment effects," *Journal of Business and Economic Statistics*, 29, 1–11.

ADAMS, C. P. AND V. V. BRANTNER (2006): "Estimating The Cost Of New Drug Development: Is It Really $802 Million?" *Health Affairs*, 25, 420–428.

ANGRIST, J. D. AND J. S. PISCHKE (2008): *Mostly Harmless Econometrics: an Empiricist's Companion*, Princeton University Press.

BAO, Y., A. T. SHAO, AND D. RIVERS (2008): "Creating New Brand Names: Effects of Relevance, Connotation, and Pronunciation," *Journal of Advertising Research*, 48, 148.

COSTABLE JR, J. AND M. MCKINLEY (1996): "Prozac or Prilosec for Gastric Ulcer?" *New England Journal of Medicine*, 335, 600–600.

DE BENEDETTI, F., M. CLAYTON, H. SHIRE, AND D. STONE (2006): "Meeting the pharma challenge," *World Trademark Review*, 52–60.

ELLERIN, B. AND J. BREEN (2006): "The rigors of regulatory approval," Tech. rep., Interbrand Health.

HO, D. AND D. RUBIN (2011): "Credible Causal Inference for Empirical Legal Studies," *Annual Review of Law and Social Science*, 1–36.

IMBENS, G. AND D. RUBIN (2011): *Causal Inference in Statistics and Social Sciences*, Mimeo.

IMBENS, G. AND J. WOOLDRIDGE (2009): "Recent developments in the econometrics of program evaluation," *Journal of Economic Literature*, 47, 5–86.

KENAGY, J. W. AND G. C. STEIN (2001): "Naming, labeling, and packaging of pharmaceuticals," *American Journal of Health-System Pharmacy*, 58, 2033–2041.

KOHLI, C. AND D. W. LABAHN (1997): "Creating effective brand names: A study of the naming process," *Journal of Advertising Research*, 37, 67–75.

KOHN, L. T., J. CORRIGAN, M. S. DONALDSON, AND INSTITUTE OF MEDICINE (U.S.). COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA (2000): *To Err is Human*, Building a Safer Health System, National Academy Press.

KUR, A., R. HILTY, AND R. KNAAK (2011): "Study on the Overall Functioning of the European Trade Mark System," Tech. rep., Max Planck Institute for Intellectual Property and Competition Law Munich.

LALLEMAND, J. (2011): "Pharmaceutical Trademarks: How to Survive the Name Game," Tech. rep., Thomson Compumark.

LANDES, W. M. AND R. A. POSNER (1987): "Trademark Law: An Economic Perspective," *Journal of Law and Economics*, 30, 265–309.

LEUVEN, E. AND B. SIANESI (2003): "PSMATCH2: Stata module to perform full Mahalanobis, and propensity score matching, common support graphing and covariate imbalance testing." http://ideas.repec.org/c/boc/bocode/s432001.html, version 1.2.3.

RAFFALLI, J., J. NOWAKOWSKI, AND G. P. WORMSER (1997): ""Vira something": a taste of the wrong medicine," *The Lancet*, 350, 887.

VON GRAEVENITZ, G., C. GREENHALGH, C. HELMERS, AND P. SCHAUTSCHICK (2012): "Trade Mark Cluttering: An Exploratory Report Commissioned by UKIPO," Tech. rep., UKIPO.

WICK, J. Y. (2011): "Why Is It Called That? Tongue-Twisting Taxonomy," *The Consultant Pharmacist*, 26, 544–552.

WOOLDRIDGE, J. M. (2002): *Econometric analysis of cross section and panel data*, Cambridge, Mass.: MIT Press.

8 Appendix

8.1 Mathematical Appendix

Here I set out the detailed analysis under pinning the statement made in Section 3 of the paper. First, I analyze the second stage decision of how many names to apply for under a regulatory regime in which the probability that names are rejected is low: (μ_l).

As noted in Section 3 firms that have innovated successfully at Stage 1 choose the number of trade marks M_l to maximize the following value function:

$$V_M = (1 - \mu_l^M{}_l)\bar{\pi} + \mu_l^M{}_l\pi - C \cdot M \tag{5}$$

The optimal number of trade marks to register $(\hat{M}_l)$ is implicitly defined by:

$$\mu_l^{\hat{M}_l} = -\frac{C}{(\bar{\pi} - \pi)\ln \mu_l} \quad . \tag{6}$$

An interior maximum exists as $\frac{\partial^2 V_M}{\partial M^2} = -(\bar{\pi} - \pi)(\ln \mu_l)^2 \mu_l^M < 0$.

Proposition 1 states that firms will apply for more invented names, if the probability that invented names are rejected increases and if this probability remains below a threshold probability $\bar{\mu}$. To see this consider a probability of name rejection μ_l', where $\bar{\mu} > \mu_l' > \mu_l$. Applying the implicit function theorem, I establish how an increase in the probability that names are rejected affects the number of names chosen by a firm. The sign of this effect is determined by the sign of the following cross-derivative: $\frac{\partial^2 V_M}{\partial M \partial \mu_l'} = -(\bar{\pi} - \pi)\mu_l^{M-1}(1 + M \ln \mu_l)$. The number of trade marks registered will increase in the probability of rejection, if and only if $(M \ln \mu_l' + 1) < 0$. Inserting the first order condition to substitute out M_l the upper bound $\bar{\mu}_l$ can be derived.

At stage one of the game firms set the probability of innovation to maximize this value function:

$$V_R = pV_M(\hat{M}_l, \mu_l) + (1 - p)\underline{\pi} - \gamma(p) \quad . \tag{7}$$

The optimal level of R&D investment is determined by this condition:

$$V_M(\hat{M}_l, \mu_l) - \underline{\pi} = \frac{\partial \gamma}{\partial p} \Leftrightarrow (\bar{\pi} - \underline{\pi}) - \left[(\bar{\pi} - \pi)\mu_l^{\hat{M}_l} + C\hat{M}_l\right] = \frac{\partial \gamma}{\partial p} \quad . \tag{8}$$

Note that the marginal benefit of R&D investment consists of two elements here. The first element is the loss of profits that arises, if the firm does not innovate at all. The second, in square brackets, captures the effects of name regulation on the probability of obtaining at least one name.

The assumptions on the R&D cost function imply an interior maximum exists, as $\frac{\partial^2 V_R}{\partial p^2} = -\frac{\partial^2 \gamma}{\partial p^2} < 0$.
Now consider how the level of R&D investments varies with the toughness of name regulation. The following result can be proved:

Proposition 2
Firms' R&D investments always decrease, if name regulation is toughened.

To see this, note that: $\frac{\partial^2 V_R}{\partial p \partial \mu_l} = \frac{C\hat{M}_l}{\mu \ln \mu} < 0$. By the implicit function theorem, this result implies that tougher name regulation always decreases firms' R&D investments, which will reduce the number of successful drug trials.
Next I show that the observed average number of simultaneous names applied for in pharmaceutical Nice classes $\bar{n}$ will fall as a result. First, note that firms also apply for names that do not apply to products vetted by the NRG in pharmaceutical Nice classes. Assume that the number of trade mark application events not related to NRG name review is O and is unaffected by changes in the name review regime. The number of trade mark application events affected by name review is N. If firms are unaffected by name review they apply for one name per product whereas firms affected by name review apply for M names per drug. Then the average number of simultaneous names applied for in pharmaceutical Nice classes is $\bar{n} = \frac{O+N \cdot M}{O+N}$. This average is increasing in M and N. A reduction in R&D activity, which lowers N will also lower $\bar{n}$. This is a testable implication of the modelcaptured in Hypothesis 2.

Identifying the Proportion of Surplus Marks Here I demonstrate how the theoretical model can be combined with the estimated effect of EU enlargement ($\hat{\tau}_p$) to identify the number of surplus trade marks applied for by pharmaceutical firms in Europe. In each set of marks that are connected to a single product, all but one of the marks are surplus. If a mechanism existed to identify and remove these surplus marks, the costs of creating new marks would be lower.
In this section expressions for the number of surplus applications before and after EU enlargement are derived. In the following section I show how these expresions can be combined with the data used for this study to calculate the total costs of creating the surplus trade marks. In the paper I discuss how this cost relates to the costs of not removing surplus trade marks from the trade mark register.
In this section I simplify to two periods: the period before EU enlargement and the period immediately after it. In this second period firms adjust the number of names they apply for but not the yet the level of R&D investment. The two periods are denoted by l, h.
To begin with I reexpress the number of application events affected (N) and unaffected (O) by name review in pharmaceutical Nice classes as fractions of

the total number of application events (A) in those Nice classes:

$$\bar{n}_l = \frac{Om_l + NM_l}{N+O} = \frac{\lambda A m_l + (1-\lambda)AM_l}{A} = \lambda m_l + (1-\lambda)M_l \quad , \quad (9)$$

$$\bar{n}_h = \frac{Om_h + NM_h}{N+O} = \frac{\lambda A m_h + (1-\lambda)AM_h}{A} = \lambda m_h + (1-\lambda)M_h \quad , \quad (10)$$

where λ is the proportion of total application events that is not related to name review. Note that I assume N and thereby λ remains constant after EU enlargement as firms will not yet have been able to adjust their R&D expenditure to higher costs of name review. A is observable, while λ is not and must be derived from the model. I assume that m_l, m_h are observable in classes not related to pharmaceuticals applications and are different across periods because of effects unrelated to EU enlargement. If m_l, m_h differ from 1, then this reflects marketing or other considerations as discussed in Section 4.

The empirical models above estimate the increase in the average number of simultaneous applications in pharmaceutical Nice classes that is due to EU enlargement; call this $\tilde{\tau}_p$. It follows from the defintion of the treatment effect in DID models (Angrist and Pischke, 2008) that:

$$\tilde{\tau}_p = (\bar{n}_h - \bar{n}_l) - (m_h - m_l) \quad . \quad (11)$$

Substituting out $\bar{n}_h, \bar{n}_l$ in Equation (11):

$$\begin{aligned} \tilde{\tau}_p &= (\lambda m_h + (1-\lambda)M_h - [\lambda m_l + (1-\lambda)M_l]) - (m_h - m_l) \\ \Leftrightarrow \tilde{\tau}_p &= (1-\lambda)[(M_h - M_l) - (m_h - m_l)] \\ \Leftrightarrow (1-\lambda) &= \frac{\tilde{\tau}_p}{[(M_h - M_l) - (m_h - m_l)]} \quad . \end{aligned} \quad (12)$$

Using the definitions of n_l, n_h and the above result it can be shown that:

$$\begin{aligned} (\bar{n}_h - m_h) &= (1-\lambda)[M_h - m_h] \\ \Leftrightarrow (\bar{n}_h - m_h)[(M_h - M_l) - (m_h - m_l)] &= \tilde{\tau}_p[M_h - m_h] \\ \Leftrightarrow M_h(\bar{n}_h - m_h - \tilde{\tau}_p) &= [M_l + (m_h - m_l)](\bar{n}_h - m_h) - m_h\tilde{\tau}_p \\ \Leftrightarrow M_h = [M_l + (m_h - m_l)]\frac{(\bar{n}_h - m_h)}{(\bar{n}_h - m_h - \tilde{\tau}_p)} &- \frac{m_h}{(\bar{n}_h - m_h - \tilde{\tau}_p)}\tilde{\tau}_p \quad . \end{aligned} \quad (13)$$

The first order conditions for Stage II of the model implictly define the number of simultaneous trade mark applications made by firms before and after EU enlargment:

$$\mu_l^{M_l} = -\frac{C}{(\bar{\pi} - \pi)\ln \mu_l} \qquad \mu_h^{M_h} = -\frac{C}{(\bar{\pi} - \pi)\ln \mu_h} \quad . \quad (14)$$

Note that none of the variables in these expressions are observable. Combining the two first order conditions yields:

$$\begin{aligned} M_l \ln \mu_l + \ln(-\ln \mu_l) &= M_h \ln \mu_h + \ln(-\ln \mu_h) \\ \Leftrightarrow M_h &= \frac{1}{\ln \mu_h}\left(M_l \ln \mu_l + \ln(-\ln \mu_l) - \ln(-\ln \mu_h) \right) \end{aligned} \tag{15}$$

where I assume that $\frac{C}{(\bar{\pi}-\pi)}$ is constant over time.
To connect the model to observable information about name review I assume that every country agency taking part in name review has the same probability of accepting a name. Call this probability ρ. Then $\mu_l = 1-\rho^{15}$ and $\mu_h = 1-\rho^{25}$. Next observe that given information about ρ we can use Equations (15) and (13) to solve for M_l:

$$\begin{aligned} \frac{1}{\ln \mu_h}\left(M_l \ln \mu_l + \ln(-\ln \mu_l) - \ln(-\ln \mu_h) \right) = \\ \Big[M_l - m_l \Big] \frac{(\bar{n}_h - m_h)}{(\bar{n}_h - m_h - \tilde{\tau}_p)} + m_h \end{aligned} \tag{16}$$

which leads to:

$$M_l = \left[\tfrac{(\bar{n}_h - m_h)}{(\bar{n}_h - m_h - \tilde{\tau}_p)} - \tfrac{\ln \mu_l}{\ln \mu_h} \right]^{-1} \left(\tfrac{(\ln(-\ln \mu_l) - \ln(-\ln \mu_h))}{\ln \mu_h} + m_l \tfrac{(\bar{n}_h - m_h)}{(\bar{n}_h - m_h - \tilde{\tau}_p)} - m_h \right) \tag{17}$$

This shows that the assumption that ρ is the same across countries and information on ρ or either μ_l, μ_h will suffice to calculate M_l, M_h.

The number of surplus trade marks I begin this section by considering the assumption that ρ is constant across countries. Lallemand (2011) reports the range of acceptance probabilities for invented names by the NRG before and after EU enlargement: before enlargement this ranged from 54% to 70%, while it fell to around 52% in the period immediately after enlargement.
Taking this last value as a starting point I calculate that $\rho = 0.9742$ and that therefore the probability of rejection before enlargement should be 0.6755. This latter value is above average but within the range reported by Lallemand (2011), so that the assumption seems defensible. In what follows I assume that $\rho = 0.9742$.
Next I use Equations (13) and (17) to calculate M_l, M_h. To do this I need information on the following variables: $m_l, m_h, \bar{n}_h$ and $\tilde{\tau}_p$. I use the estimated effect of EU enlargement in the anticipation period as estimated in the outlier cor-

rected regression here: $\tilde{\tau}_p = 0.061$. I use the outlier corrected model to ensure that large application events, which are unlikely to be connected to introduction of individual new drugs do not affect my analysis. Restricting the sample to the outlier corrected set of observations I find that $m_l = 1.186723$, $m_h = 1.18012$ and $\bar{n}_h = 1.252024$. These numbers are means for the period before 2001 in the case of m_l and for the period between 2001 and EU enlargement for the other two variables.
Inserting these values into Equation (17) I find that $M_l = 1.19801$, slightly above m_l, as might be expected. Moving on to Equation (13) I find that $M_h = 1.2545496$ which represents a significant increase over m_h, if we compare $(M_h - m_h)/m_h = 0.063$ to $(M_l - m_l)/m_l = 0.0095$. Finally, Equation (12) implies that $(1 - \lambda) = 0.9661$.
In the period before 2001 there were 28418 applicantion events in the Nice classes relevent to ethical drugs. In the period between 2001 and EU enlargement there were another 27065. The number of surplus marks can be calculated as $A(1-\lambda)(M_j - m_j)$ where $j \in \{l, h\}$. This implies that pharmaceutical firms created 310 surplus marks before 2001 and 1946 surplus marks between 2001 and EU enlargement. Assuming that each mark cost US $ 25,000 this amounts to a total expense of slightly over US $ 56 million and of US $ 17.7 million per year, between 2001 and 2004.

8.2 Matching

To capture the anticipation of European Enlargement that manifests itself in the DiD results reported above, I provide further results controlling exactly also for the pre 2001 average of simultaneous applications. This should allow for even more precise matching of treated firms to firms in the control sample. The unconfoundedness assumption should be even less problematic here. As is reported in Table 6 below this reduces the percentage of cases matched very slightly.
Overall the coefficients reported in Table 6 are very similar to those reported in Table 5 above. The differences between the coefficients are never statistically significant.
Using the same calculation as previously, an extrapolation of the most conservative robust PATT estimator reported here suggests that invented name review increased trade mark applications in pharmaceuticals Nice classes at OHIM by $38\%(= 2.5 \times 15.29)$. This corresponds to 5941 surplus trade marks in pharmaceuticals Nice classes and costs of invention of US $148.5 million in 2009.
The estimates reported here are robust to covariate imbalances, but may be biased if a sample selection problem remains, in spite of controls for pre-2004 and pre-2001 average simultaneous trade mark applications.

Table 6: Results from Matching Estimators

Number of matches	PATT	Robust, Bias adjusted	PATE	Robust, Bias adjusted
1	0.1676***	0.1796***	0.1059***	0.0340
	(0.0444)	(0.0404)	(0.0303)	(0.0269)
	52.58%		56.96%	
4	0.1383***	0.1529***	0.1138***	0.0754***
	(0.0379)	(0.0363)	(0.0286)	(0.0261)
	43.90%		49.20%	

N=21162

† p<0.10, * p<0.05, ** p<0.01, *** p<0.001. Standard errors in parentheses,

Note that I have also estimated the PATT set out in Table 5 above with 1 match using the bias adjustment with a random subsample of 50% of the population. The coefficient I estimated from this random subsample is 0.1710 with a standard error of 0.0187. The result is statistically indistinguishable from that reported above. Obtaining the coefficient took five times longer - 12 days - than the regressions reported above, so that I did not attempt matching with the entire population.

Also note that in general the estimates of the PATE reported in Table 5 are insignificant once the bias adjustment is used. Since the interpretation of this effect is unclear in this setting, as I argued above, this does not matter.