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# European patent opposition outcomes in biotechnology

Lorena M. D'Agostino, Lorenzo Tiraboschi *, Salvatore Torrisi

*University of Milano-Bicocca, Piazza dell'Ateneo Nuovo, 1, 20126, Milano, MI, Italy*

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ABSTRACT

Oppositions to patent grants are a means to attack competitors and protect a firm's own patent portfolio. Extant literature has analyzed the determinants of oppositions, while the drivers of opposition outcomes are less known. We study 290 EPO biotech patent oppositions filed in 2012–2019. There are three possible outcomes of opposition proceedings: patent revocation, patent amendment, and opposition rejection. We find that opponents who know the patent's technology are more likely to obtain a patent revocation, while opponents who compete in the product market with the patent owner are more likely to receive a rejection.

## 1. Introduction

This paper analyses the characteristics of biotechnological patents that have received opposition before the European Patent Office (EPO). Patents are crucially important means to protect biotechnological inventions since R&D activities absorb considerable financial resources and take a long time, regulatory and ethical issues are strongly dominant, and other means of intellectual protection (such as trade secrecy) are less effective. Biopharmaceuticals and other applications to medicine (*red* biotechnology) in particular are characterized by high uncertainty and a long time from the early stage of emerging biotechnologies to their commercialization [1].

Given the importance of patents as a means for appropriating the value of innovation in biotech, innovators engage in various activities to attack or protect their patented inventions from competitors. Among these activities, oppositions against granting decisions before the EPO are a mechanism for first-instance challenges to the validity of patents. Any third party can file an opposition within 9 months from the granting date of the patent and the outcome of the patent opposition is binding for all designated states. The decisions on oppositions are open to appeals at the independent Boards of Appeal, which is the first and final judicial instance in the procedures before the EPO. Both patent holders and opponents can appeal to the Board; this further step increases the cost of any party involved in terms of additional fees, patent attorneys' remuneration, and increased uncertainty [2]. Any further challenge to the validity of a patent needs to be done in national courts. Third parties may also challenge the validity of a patent directly in national courts, which in some cases proves to be a faster but also less effective way than oppositions [3]. However, oppositions are less costly and time-consuming compared with litigation before national courts, and the EPO decisions extend to all states adhering to the European Patent Convention (EPC). This may explain the substantial share of biotech patents attacked in opposition proceedings [4]. About 8.6% of biotech patents granted by the EPO are opposed [4] while the share of overall EPO patents opposed varies between 5.3% and 5.5% [5].

The outcome of an opposition - either as first instance or as the result of an appeal at the Board (e.g., patent revocation or amendment) - may have important consequences for the market position and competitive advantage of the patent owner (defendant) and its competitor (opponent). An important reason for a firm to engage in patent litigation is retaining the freedom to operate and commercialize its invention without being blocked by patents owned by others [6]. Innovators assess their freedom to operate by screening the patent landscape and in case they identify a potentially blocking patent that entails a high risk of litigation they may abandon the inventive project. The discovery of blocking patents may lead an inventor to attempt to enter licensing or cross-licensing negotiations with the owner of conflicting patents to avoid a patent infringement lawsuit (a defensive strategy) [6]. However, licensing is not always a viable solution and the parties often fail to reach an agreement because of transaction costs associated with bargaining complexity and information asymmetry [7]. Thus, a third party may try to invalidate the conflicting patent to retain the freedom to operate. Besides the freedom to operate, patent owners may screen for infringing products or activities, which spur them to file an infringement lawsuit to assert their patent rights in court or to file an opposition to challenge the validity of a rival patent if the patenting procedure has not properly

* Corresponding author.
*E-mail addresses:* lorena.dagostino@unimib.it (L.M. D'Agostino), lorenzo.tiraboschi@unimib.it (L. Tiraboschi), salvatore.torrisi@unimib.it (S. Torrisi).

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taken into account pre-existent knowledge on the subject.

For these reasons, innovation scholars and practitioners have been interested in understanding the characteristics of opposed patents [4,8] and the drivers of the outcome of opposition [8,9]. Yet, the evidence on the factors related to opposition outcomes is limited, especially in biotechnologies. We intend to fill this gap by proving novel empirical evidence about the factors associated to different opposition outcomes of patents owned by top players in the bio-pharma sectors. In particular, we focus on the role of competition, which has been overlooked in earlier studies on patent opposition, despite being crucial in the strategic management of patents, [7,10].

We analyze the oppositions received by biotech patents granted by the EPO and owned by the largest firms operating in "pharmaceutical preparations" (US SIC 2834) and "commercial physical and biological research" (US SIC 8731) in the period 2012–2019 [11,12]. As we explain later, our sampling of opposed patents begins by searching for patents held by companies whose cumulative revenues account for about 60% of the two industrial sectors. Biotech patents were identified through international patent classification (IPC) codes as in OECD [13]. The sample starts in 2012, when the revolutionary CRISPR-Cas9 technology was firstly incorporated in a patent application, which has shaken the biotech patent landscape and gave rise to significant legal disputes [14, 15]. Our sample selection procedure generates mostly patents in biopharma and biomedicine fields ("red biotech") while a smaller share of patents pertains to agricultural applications ("green biotech") and other biotech applications [16].

The focus on oppositions received by biotech patents granted by the EPO is justified by the and the rising economic importance of the EPO due to the large number of applications and patent grants. Moreover, as mentioned before, the EPO opposition system is a more established and less costly means of challenging the validity of patents compared with other systems like that valid in the USPTO before the adoption of a post-grant review in 2011. These advantages make European patenting particularly attractive for applicants operating in international markets [4]. Finally, most firms in our empirical setting compete in different geographical markets and, as other multinational firms, "*prefer to litigate in the few countries with substantial track records to send strong signals to competitors elsewhere*" [17] (p. 53). The outcome of opposition in the EPO then can have significant implications for litigation in other markets.

The paper is organized as follows. Section 2 illustrates the conceptual background. Section 3 presents the data and the method, and Section 4 discusses the variables. A descriptive analysis is provided in Section 5, and the results of the econometric analysis are provided in Section 6. Finally, Section 7 presents the conclusions and the limits of our research.

## 2. Patent opposition from a competitive dynamics perspective

Our analysis of patent oppositions draws on the competitive dynamics perspective. In carrying out their activities and making their decisions firms consider the (potential or actual) action or reaction of their competitors and interact with other parties to ensure the resources they need to operate and succeed in the product market. Competitive dynamics thus *"is the study of interfirm rivalry based on specific competitive actions and reactions, their strategic and organizational contexts, and their drivers and consequences"* [18] (p. 137). The interdependence and interaction between firms lie at the heart of competitive strategy and represent the basis of competitive dynamics [19]. In science and technology-based sectors like biotechnology, firms interact in both the technological and the product markets. Despite the differences between these two markets, the underlying competitive logic is similar as the success in the technological race often reverberates on a firm's position in the product market. From a competitive dynamics perspective, patent oppositions can be viewed as the reaction to the action of rivals (i.e., patenting to protect a technology from imitation or to preempt substitute innovations).

Earlier studies deal with the issue of patent oppositions from different theoretical perspectives. For example, Harhoff and Reitzig [4], analysing the determinants of oppositions to biotechnology and pharmaceutical patents granted by the EPO, found that the density or crowdness of patent grants within a technical field (measured by the cumulative number of patents in the same four-digit IPC field) increases the likelihood of overlapping claims thus affecting the likelihood of oppositions. Crowdness increases the awareness of a patent especially among rival firms. Harhoff and Reitzig [4] also found that the likelihood of receiving an opposition increases with the economic value of a patent measured, for example, by family size (i.e., the number of patent applications that share the same priority claims) and forward citations (i.e., the number of cites received by the patent). Patent value motivates oppositions as rivals recognize that *"something important is at stake"* [20] (p. 86). The connection between oppositions and patent value is underlined by van de Kuilen [5], who noted that an opposition is an indicator of the importance of a patent. These findings were confirmed by Caviggioli, Scellato and Ughetto [8]. Moreover, oppositions are more likely the greater the grant lag, a measure of uncertainty and complexity of the subject matter, and the larger the number of X-Type or Y-Type backward citations (i.e., citations to earlier patents whose claims overlap completely or partially with the claims of the focal patent application), a measure of weakness or uncertain validity of the paper [10], which may favour a rival's ability to oppose successfully to the patent grant.

Instead, the size of the applicant's patent portfolio decreases the likelihood of opposition for two reasons. First, a larger patent portfolio eases settlement via licensing or cross-licensing and, second, the owner of a large patent portfolio is in the position to retaliate against the attacker. Harhoff and Reitzig [4] also noted that firms with large patent activity are likely to be engaged in repeated interactions with rivals, which favours settlement and reduces the incentive to litigate.

To our knowledge, only few earlier studies have focused their attention on the outcome of oppositions, i.e., revocation, amendment, rejection and opposition withdrawal. For instance, van de Kuilen [5] studied patent oppositions outcomes in the time interval 2010–2013 and found that opposed patents have the same probability of beings "revoked", "amended" or remaining "unchanged" [5]. A similar distribution of opposition outcomes was found in other studies [4,8].

The evidence of the determinants of the outcome of oppositions is still limited (e.g., Ref. [8]).

Following the aforementioned studies, we address the question as to what factors are associated with the outcome of a patent opposition, given that an opposition to the patent has been filed at the EPO. This is a relevant question from a theoretical and practical perspective, as the outcome of an opposition procedure (e.g., patent revocation or amendment) is likely to affect the patent owner's ability to appropriate the benefit of the underlying invention and the opponent's freedom to operate in the product market.

Our analysis takes into account various dimensions related to competitive links between opponents and the owners of opposed patents that, to the best of our knowledge, have not been considered in previous studies on patent oppositions. More precisely, as measures of technological competition we consider citation links (i.e., whether the opposed patent cites opponents' patents) and cross-oppositions between the opponents and the defendants. In particular, a citation link indicates some degree of dependence of the opposed patent on opponent's patents, which makes the opponent more conscious of the weaknesses of the opposed patents compared to other opponents, thus increasing the probability of opposition success. Cross oppositions capture the competitive dynamics dimension in our analysis since they represent a series of "attacks" and "counterattacks" between competing companies. However, the impact of cross-oppositions is more difficult to predict. We also look at opponents and defendants home country. Companies based on the same country may have a greater knowledge of the opposed patents and its potential applications, which may give the opponent an informational advantage compared with a foreign party and increase its capability to file a successful opposition. To account for the effect of market competition, we examined the products offered by opponents and defendants. The interaction in the product market increases awareness and motivation and may give an informational advantage to opponents.

Some variables that affect the probability of oppositions are likely to also affect the outcome of oppositions. Patent value affects the motivation for filing an opposition, but it could reduce the likelihood of patent revocation, i.e., it reduces the probability that an opponent would succeed in responding to the patent owner's action. There exist various measures of patent economic value such as family size, the number of citations, number of claims, and number of IPC classes. Patent family size and the number of claims at the time of grant reflect the expected economic value of a patent. The number of claims has a controversial interpretation. Studies on the determinants of legal disputes do not agree whether this is a measure of value (a larger scope of applications leads to higher potential profitability) [21] or uncertain validity or complexity of the examination process [4]. While the value of the patent arising from a large scope of applications motivates the opposition, conditional on opposition, uncertainty and complexity of examination process could increase the likelihood of amendment aiming to reduce the scope of applications. The number of technological (IPC) classes, a measure of technical scope, is often associated to value, like the number of citations received (e.g., Ref. [22]). According to Lerner [22] as the number of IPC classes increases, the value of the patent increases and the probability of opposition also increases. However, the number of IPC classes may also be a measure of ambiguity reflecting the difficulty of the examiner in locating the invention in the technological space [23]. Moreover, a large number of IPC classes indicates that the invention is more "general" and therefore more distant from the commercial application, which may decrease the probability of opposition [4]. While the ambiguity signalled by many IPC classes makes the success of an opposition more likely, the generality has a less clear effect on the outcome of an opposition. The literature considers various measures of patent 'quality' such as grant lag, an indicator of the level of uncertainty and complexity of the examination process, which may increase the likelihood that the patent is amended or revoked after opposition [8].[1] As mentioned before, Harhoff and Reitzig [4] found that the number of X-type or Y-type backward citations increases the likelihood of an opposition. It could also increase the likelihood of success of the opponent (i.e., patent amendment or revocation) since X-type and Y-type references signal weakness of the patent, i.e., arguable novelty and/or inventive step [10].

Finally, as discussed above, firms with large patent portfolios are less likely to receive an attack by an opposition. However, conditional on opposition, it is not clear how the size of the patent assignee (a proxy for its relative bargaining power) may affect the outcome of the opposition process since the EPO is entitled to decide on the case even if the opponents withdraw the opposition.

## 3. Data and method

### 3.1. Sample

To build our final sample of opposed patents, firstly we searched the European companies in the Bureau van Dijk's Amadeus dataset [24] classified in two sectors: pharmaceuticals ("pharmaceutical preparations", SIC class 2834), which make a great use of biotechnology to develop new products and "modernize" their pipeline; and biotechnology ("commercial physical and biological research", SIC class 8731). We found 66,659 firms and decided to focus on the top players. Thus, we selected the companies whose cumulative revenues account for about 60% of the total revenues of the two sectors, which are 97 companies (*top players* from now on).

As a second step, we searched these firms in the European Patent Register [25] and collected data on their oppositions (filed in 2012–2019) to biotech patents [26,27]. Biotech is defined as in Ref. [13] (p. 32).[2] Seventeen of the *top players* filed a biotech opposition. For these opposed patents we extracted the names of the assignees. In some cases, the assignees were in the list of the seventeen *top players*. In all the other cases (hereinafter *first-order links to top players*), we collected their biotech oppositions and the patent assignees. Some of these assignees were either *top players* or *first-order links of top players*.

Therefore, the final sample is made of biotech patents

1) opposed by *top players*;
2) opposed by *first-order links* and owned by *top players*;
3) opposed by *first-order links* and owned by other firms.

We obtained 319 oppositions to 305 patents. After eliminating ongoing oppositions, we ended up with 290 patents receiving at least one opposition. Most of these cases (i.e., 62%) have been appealed after the first-instance opposition decisions, either by the patent holder or by the opponents. Therefore, opposition outcomes in our dataset are originated by either opposition divisions or the Board of Appeal. Data on firms and patent characteristics were obtained from company websites and various datasets ([28–32]).

Our sample of patent oppositions is biased in favour of large biotech and pharma companies, while purely biotech firms are underrepresented. This also implies that most patents are classified as "red biotech" (i.e., related to health), while "green" (i.e., relative to agriculture and livestock) and "white" (i.e., relative to industrial processes) are less represented.

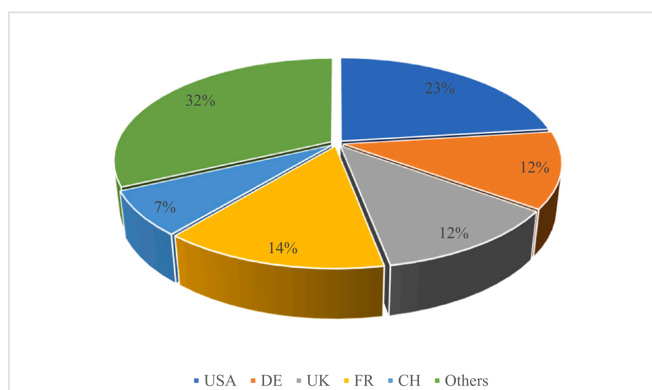


**Fig. 1.** Sample firms by nationality of the parent company (n = 97).

[1] The patent literature distinguishes between patent value and patent quality. Patent value refers to the economic or monetary value of a patent, measured, for example, by forward citations and family size. Instead, patent quality is about the legal strength (e.g., the novelty or inventive step and references to the relevant prior art) of a patent. A patent opposition may help re-examine whether a granted patent satisfies the patentability requirements.

[2] Biotechnology encompasses various research technologies or methods and several fields of applications such as transgenic vertebrates, invertebrates and plants; methods, processes and testing; bioinformatics; biological materials. The full list of IPC classes covering these technologies is the following: A01H 1, A01H 4, A61K 38, A61K 39, A61K 48, C02F 3/34, C07G 11, C07G 13, C07G 15, C07K 4, C07K 14, C07K 16, C07K 17, C07K 19, C12 M, C12 N, C12P, C12Q, C12S, G01 N 27, G01 N 33/53*, G01 N 33/54*, G01 N 33/55*, G01 N 33/57*, G01 N 33/68, G01 N 33/74, G01 N 33/76, G01 N 33/78, G01 N 33/88, G01 N 33/92 [13] (p.32).

As Fig. 1 shows, the ultimate parent company of 23% of the sample firms is based in the United States and the 45% in four European countries, while the rest of firms is based in countries such as Israel, India, China and Japan.

## 4. Variables

In this Section we briefly describe the variables used in our analysis.

### 4.1. Dependent variables

We have two dependent variables that build on the possible outcomes of an opposition against patent grants - i.e., patent revocation, patent amendment, opposition withdrawal, opposition rejection. Our first dependent variable is *defence success*, which is equal to 1 if the opposition is rejected (or withdrawn) and the patent is maintained as granted or the patent is maintained in an amended form; it is equal to 0 if the patent is revoked. We also use the categorical variable *opposition outcome* to identify three possible results of the opposition case: patent revocation, patent amendment, opposition rejection or withdrawal.

### 4.2. Independent variables

To assess whether the opposition outcome is related to competition, we use a set of variables related to both technology and market competition. We use *same home,* which is a dummy variable that indicates whether at least one opponent belongs to the same country as the assignee (or at least one co-assignee). *Citation link* is a dummy variable that indicates whether the opposed patent cites at least one patent owned by an opponent. *Same home* and *citation link* thus indicate how well an opponent knows the underlying technology of the opposed patent, its possible flaws or limited validity. We also control for whether the firms compete in product markets. *Competitor* is a binary variable that indicates whether the opponents and the defendants belong to the same biotech field of application.[3] We rely on the classification of biotech applications illustrated by Ref. [33] (p. 5). Finally, we use *cross opposition* which is a binary variable equal to 1 if the patent has at least one opponent and one defendant involved in multiple opposition actions in our sample.

In studying the association between the outcome of oppositions and competition, we account for various controls at the firm and the patent level. To see whether different opposition outcomes depend on the size of the defendant, we introduced two measures of size: *firm size* (number of employees) and *patent portfolio*. Both variables are constructed in the year preceding that of the first opposition received by the assignees in our sample. In the case of multiple assignees, we used the number of employees and the patent portfolio of the largest co-assignee. As mentioned before, the effect of a larger patent portfolio on opposition outcomes are not easy to predict [8].

To control for patent characteristics, we use the number of cited documents (*citations*), as well as the number of X- and Y-types of documents (*X–Y citations*). Moreover, we use the number of patents in the same patent family (*family size*) as a proxy for the economic value of the patent. We also control for the lag between application and grant decision (grant *lag*), a measure of complexity of the patent subject. As discussed before, the number of IPC classes of the opposed patent (*number of IPC classes*) is a measure of patent value (e.g., Ref. [22]), generality [4] or ambiguity [23]. While earlier work on biotechnology has found a negative correlation between the number of IPC classes and the likelihood of opposition [4], we do not have strong expectations about the implications for the outcome of opposition, given that an opposition is filed. As an additional measure of patent value, we employ the number of *claims*, which has been found positively correlated with opposition likelihood, and negatively correlated to revocation outcome [8].

To control for different areas of application of the patents, we used the colour-based classification of biotechnologies proposed by Ref. [33] (p. 5), and we control for the most frequent area in our sample, namely *red biotech* (Biomedicine, Biopharmaceutics, Diagnostics) [33]. We also use dummies for specific IPC classes [4]: A61K38 (medicinal preparations containing peptides), AK639 (medicinal preparations containing antigens or antibodies), C12M (apparatus for enzymology or microbiology), C12N (microorganisms or enzymes; composites thereof), C12P (fermentation or enzymeusing processes), and C12Q (measuring or testing processes involving enzymes).

The binary variable *appeal* controls for whether the decision has been taken by the Board of Appeal or by the first-instance opposition division.

Finally, we introduced a set of country dummies that indicate whether an assignee is based on one of the following countries: United Stated, Germany, France, Great Britain, Japan, or Switzerland.

## 5. Descriptive statistics

Because of missing values in some variables, our final sample consists of 266 observations. In 139 cases (i.e., 52% of the sample) the patent has been revoked, in 79 cases (i.e., 30%) the patent has been maintained with some amendments, in 12 cases (i.e., 4%) oppositions have been withdrawn,[4] while in 36 cases (i.e., 14%) the opposition has been rejected.

Table 1 provides summary statistics of the variables presented in previous section.

Cross oppositions concern 20% of the cases. The average size of patent holders is 13 thousand employees. Some assignees, which are subsidiaries of larger corporation, have few employees - e.g., five cases have only one employee. On average, patent companies own 612.04 biotech patents, with a minimum of zero and a maximum of 3,590 patents.

On average, each patent contains 3.26 backward patent citations and 2.15 X–Y backward citations. The average family size is equal to 43.82 patents and the average application-grant lag is 3043.47 days (roughly 8.3 years).

On average, patents are classified in 3.5 IPC classes. The majority of sample patents (86%) are classified in at least a red class. The most frequent IPC class (39% of cases) is A61K39 (med. preparations with antigens or antibodies). The most frequent home countries of the applicants of opposed patents are Great Britain (14%) and Switzerland (15% of cases).

Tables 2 and 3 show the relationships between the three categories of the variable *outcome* (i.e., patent revoked, patent amended, opposition rejected/withdrawn) and two explanatory variables related to competition, i.e., *same home*, and *citation link*.

Table 2 illustrates that in 191 cases (i.e., 71.8% of the sample) the opponents and the defendants have different home countries. About 36% of revoked patents are opposed by firms from the same country of the assignee, while 20% of amended patents and 18% of oppositions rejected have opponents from the same country of the defendant, which suggests a stronger relationship between *same home* and revoked patents. Indeed, the Fisher's exact test suggests that overall *same home* is correlated with the opposition outcome (p-value$<$0.05).

As for *citation link*, Table 3 shows that over 82% of patents in our sample are opposed by companies without any citation link with the focal patent. Among patents with citation links, revoked patents have the highest frequency (22%). Therefore, we might expect that patents opposed by a company whose patents are cited by the focal patent are

[3] If more firms oppose the same patent or more assignees own the opposed patent, the variable competitor is equal to 1 if at least a pair of subjects (opponent and defendant) are competitors.

[4] Withdrawn oppositions are aggregated in the category "opposition rejected" in the estimations.

**Table 1**
Descriptive statistics.

| | Obs. | Mean | Std. dev. | Min | Max |
|---|---|---|---|---|---|
| *Dependent variables* | | | | | |
| Defence success (1/0) | 266 | 0.48 | 0.50 | 0 | 1 |
| *Opposition outcome:* | | | | | |
| 1: Patent revoked | 266 | 0.52 | 0.50 | 0 | 1 |
| 2: Patent amended | 266 | 0.30 | 0.46 | 0 | 1 |
| 3: Opposition rejected/ withdrawn | 266 | 0.18 | 0.39 | 0 | 1 |
| *Independent variables* | | | | | |
| same home (1/0) | 266 | 0.28 | 0.45 | 0 | 1 |
| citation link (1/0) | 266 | 0.18 | 0.38 | 0 | 1 |
| competitor (1/0) | 266 | 0.92 | 0.27 | 0 | 1 |
| cross oppositions (1/0) | 266 | 0.20 | 0.40 | 0 | 1 |
| appeal (1/0) | 266 | 0.62 | 0.48 | 0 | 1 |
| size (employees) | 266 | 13167.53 | 32978.14 | 1 | 123686 |
| patent portfolio (parent) | 266 | 612.04 | 610.51 | 0 | 3590 |
| patent citations | 266 | 3.26 | 2.35 | 0 | 15 |
| X–Y patent citations | 266 | 2.15 | 2.09 | 0 | 11 |
| patent family | 266 | 43.82 | 70.13 | 3 | 548 |
| grant lags (days) | 266 | 3043.47 | 1141.50 | 860 | 6391 |
| number of IPC classes | 266 | 3.59 | 2.69 | 1 | 14 |
| number of claims | 266 | 17.11 | 10.19 | 1 | 70 |
| red biotech (1/0) | 266 | 0.86 | 0.34 | 0 | 1 |
| A61K38 - medicinal preparations with peptides | 266 | 0.12 | 0.32 | 0 | 1 |
| A61K39 - med. preparations with antigens or antibodies | 266 | 0.39 | 0.49 | 0 | 1 |
| C12M - apparatus for enzymology or microbiology | 266 | 0.03 | 0.16 | 0 | 1 |
| C12N - microorganisms or enzymes; composites thereof | 266 | 0.36 | 0.48 | 0 | 1 |
| C12P - fermentation or enzyme-using processes | 266 | 0.10 | 0.30 | 0 | 1 |
| C12Q -measuring or testing processes involving enzymes | 266 | 0.15 | 0.36 | 0 | 1 |
| US - assignee based on US | 266 | 0.05 | 0.21 | 0 | 1 |
| DE - assignee based on Germany | 266 | 0.09 | 0.28 | 0 | 1 |
| FR - assignee based on France | 266 | 0.02 | 0.14 | 0 | 1 |
| GB - assignee based on Great Britain | 266 | 0.14 | 0.35 | 0 | 1 |
| JP - assignee based on Japan | 266 | 0.04 | 0.20 | 0 | 1 |
| CH - assignee based on Switzerland | 266 | 0.15 | 0.35 | 0 | 1 |

**Table 2**
Country of origin of assignees and opponents, and opposition outcomes.

| | Same home | | | | | |
|---|---|---|---|---|---|---|
| | No | | yes | | Total | |
| | # | % | # | % | # | % |
| Patent revoked | 89 | 64.03 | 50 | 35.97 | 139 | 100 |
| Patent amended | 63 | 79.75 | 16 | 20.25 | 79 | 100 |
| Opposition rejected | 39 | 81.25 | 9 | 18.75 | 48 | 100 |
| Total | 191 | 71.8 | 75 | 28.2 | 266 | 100 |
| Fisher's exact (p-value) | | | | | | 0.014 |

more likely to be revoked. The correlation between outcomes and citation links is supported albeit at a quite low significance level (p-value<0.10).

Table 4 shows the distribution of outcomes by the entity that has taken the final decision. Many first-instance oppositions are appealed (166, which is 62%). The outcomes between first-instance and appeals differ slightly; it seems that the incidence of patent amendment is higher when the Board of Appeal takes the decision (36% of cases against 20% of cases in first-instance oppositions), suggesting that the two extreme decisions (patent revoked and opposition rejected) tend to be predominant in the first-instance, while the possibilities to "correct" the patent are more likely to emerge at a later phase of the opposition procedure.

**Table 3**
Citation link and opposition outcomes.

| | Citation link | | | | | |
|---|---|---|---|---|---|---|
| | no | | yes | | Total | |
| | # | % | # | % | # | % |
| Patent revoked | 108 | 77.7 | 31 | 22.3 | 139 | 100 |
| Patent amended | 67 | 84.81 | 12 | 15.19 | 79 | 100 |
| Opposition rejected | 44 | 91.67 | 4 | 8.33 | 48 | 100 |
| Total | 219 | 82.33 | 47 | 17.67 | 266 | 100 |
| Fisher's exact (p-value) | | | | | | 0.073 |

**Table 4**
Appeal and opposition outcomes.

| | First-instance opposition decision | | Board of Appeal decision | | Total | |
|---|---|---|---|---|---|---|
| | # | % | # | % | # | % |
| Patent revoked | 57 | 57 | 82 | 49 | 139 | 52 |
| Patent amended | 20 | 20 | 59 | 36 | 79 | 30 |
| Opposition rejected | 23 | 23 | 25 | 15 | 48 | 18 |
| Total | 100 | 100 | 166 | 100 | 266 | 100 |

## 6. Econometric results

We now present the results of our econometric models. First, we run a logit model to estimate the probability of a successful defence of a patent against an opposition, where *defence success* (i.e., the opposition is rejected or withdrawn, or the patent is maintained in an amended form) is the dependent variable. Secondly, we run a multinomial logit where the dependent variable *opposition outcome* can take three values: patent revoked, patent amended, opposition rejected/withdrawn.

Model 1 in Table 5 shows the results for the logit model. *Same home* is negative and statistically significant, signalling that when assignees and opponents are based in the same country, the successful defence of the patent is less likely. This result highlights an informational advantage of opponents operating in the same geographical area. Opponents based in the same country of the assignee are probably more able to detect the drawbacks and flaws that limit the validity of the patent compared with foreign opponents. *Citation link* is also negative and statistically significant, pointing out that patents opposed by the owners of cited patents are more likely to be revoked. This result is also in line with the informational advantage argument. The connections between the opponents' and assignees' patents put the opponents in a favourable position to understand the weaknesses of the patented invention (e.g., the novelty or inventive step) and challenge the validity of the patent. *Competitor* is positive and significant, pointing out that albeit competitors are probably more strongly motivated to challenge the patent, the defendant may be more able to anticipate this type of attack and prepare for an effective defence strategy. Moreover, given the limited cost of oppositions, competitors may be induced to oppose a valid patent that threatens their market position for purely strategic reasons, such as delaying the exploitation of the technology in the product market. Appeal is positive and weakly statistically significant ($p < 0.1$).

Model 2 in Table 5 shows the results for the multinomial logistic regression that allows us to estimate the log odds of the three outcomes of oppositions, with revoked patents as base category. For the variable *same home,* the results are aligned to the logit model. The negative sign on *citation link* is also in line with the results of the logit estimates, but the statistical significance is weaker. *Competitor* loses importance, as it is

**Table 5**
Econometric results: logit and multinomial logit.

| | (1) | (2) | |
|---|---|---|---|
| | Logit | Multinomial logit | |
| | DV: *defence success* | DV: *opposition outcome* (baseline: patent revoked) Patent amended | Opposition rejected |
| same home | −0.890*** | −0.747** | −1.027** |
| | (0.328) | (0.375) | (0.489) |
| citation link | −0.961** | −0.904* | −1.120* |
| | (0.402) | (0.465) | (0.628) |
| Competitor | 1.235** | 0.857 | 2.464* |
| | (0.556) | (0.552) | (1.335) |
| cross opposition | −0.213 | −0.748 | 0.377 |
| | (0.424) | (0.477) | (0.604) |
| Appeal | 0.548* | 0.975*** | −0.204 |
| | (0.304) | (0.365) | (0.410) |
| *ln* size | −0.004 | 0.020 | −0.035 |
| | (0.061) | (0.062) | (0.095) |
| *ln* patent portfolio | 0.057 | 0.045 | 0.106 |
| | (0.097) | (0.105) | (0.146) |
| Constant | 0.142 | 0.422 | −4.500 |
| | (3.256) | (3.467) | (5.113) |
| Observations | 266 | 266 | 266 |
| Prob | 0.135 | 0 | 0 |
| Adj_R2 | 0.105 | 0.163 | 0.163 |

Models include controls for: ln citations, ln X–Y citations, ln family size, ln grant lags, ln claims, number of IPC classes, red, and dummies for IPC classes A61K38, A61K39, C12M, C12N, C12P, and C12Q; dummies for the home of applicant(s) US, DE, FR, GB, JP, and CH.
All models include robust standard errors in parentheses.
*** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$.

marginally significant only for rejected oppositions. These results suggest that the negative result of *same home* in the logit model is driven both by the amended cases and rejected oppositions. Instead, the results of the other competitive factors (*citation link* and *competitor*) are milder when we disentangle the three different opposition outcomes.

Interesting, *appeal* is positive and statistically significant for patent amended, something that we already observed in the descriptive statistics in Table 4.

## 7. Conclusions and research limitations

This study focuses on the outcomes of oppositions to EPO biotech patents through the lens of the competitive dynamics perspective. We posit that some factors that influence the probability of oppositions are likely to be related also to the outcome of oppositions.

Our results provide novel evidence on the importance of competitive factors in understanding the outcomes of oppositions. First, we showed that a patent defence (i.e., maintaining a patent as granted or in an amended form) is more likely to fail when opponents know better the technology protected by the patent and thus are more able to detect the drawbacks and flaws of the patent. This happens when the opponents belong to the same country as the assignee and when the patent is opposed by the owners of cited patents. Instead, a patent defence is more likely to succeed when opponents and assignees compete in the same product market, suggesting that competitors are more likely to challenge the validity of a rival's patent for strategic reasons (e.g., delaying the introduction of a new product into the market) even when the opposed patent is valid.

Second, we distinguished partially successful defence (i.e., patent amended) from fully successful defence of the patent (opposition rejected/withdrawn) and found that sharing the same geographical origin (i.e. *same home*) has a positive strong effect in both cases while the effect of other measures of competition between opponents and defendants is more nuanced.

This paper contributes to the strategic literature on the use of patent opposition as a means to protect innovation and market positions. Oppositions are an important competitive weapon, especially in science-based fields such as biotech. So far, the literature has been interested in the factors that explain the probability of a patent opposition [4,21], while only few studies have explored the factors associated with the outcomes of patent oppositions [8,9]. However, understanding the factors associated with the outcome of a patent opposition is a relevant issue as oppositions can be used strategically to attack competitors or defend a firm's market position from competitors. We contribute to this stream of the literature by highlighting how important are the opponents' knowledge of the technology underlying the opposed patent and the interaction between opponents and defendants in the product market.

Our study is not without limitations. First, we use various indicators of patent value such as the number of IPC classes and patent family size that have several shortcomings. In future research, we will consider the effect of other measures of patent value, such as forward citations, on opposition outcomes. Most probably, more cited patents are more likely to be opposed [4], but they are also more likely to be successfully defended when opposed [34]. Second, future research should also account for references to the patent literature added during the opposition proceedings. These could also have a role in the opposition outcomes. Third, future research could investigate the association between opposition outcomes and patent use – e.g., licensing, and new product development. Fourth, our sample includes mostly large firms, while small and especially micro biotech enterprises are underrepresented. Earlier works suggest that large firms are more likely to attack smaller firms [8,35]. However, other studies (e.g., Ref. [36]) show that the holders of large biotech patent portfolios are more likely to be opposed. In future research we would like to examine more deeply the patterns of opposition and cross-opposition between large and small biotech firms. Fifth, the period of observation of our study is quite short – from 2012, the year of the CRISPR-Cas9 discovery, to 2019. In future research, we will extend the time window to compare the opposition patterns before and after the CRISPR-Cas9, a breakthrough that has contributed to change the competitive scenario of biotechnology. Sixth, our analysis is based on quantitative data which in future research could be integrated by fine-grained, qualitative data that would help gaining a deeper interpretation of results. Finally, our data do not allow to make any conclusions about causal relationship between key regressors and opposition outcomes. Although the correlations reported in the paper are interesting for an explorative study of opposition outcomes in biotech, future research could account for potential sources of endogeneity, such as omitted variables that may affect both the explanatory variables (e.g., the type of opponent or citations links) and the outcome of oppositions. Moreover, we do not control for antecedents of oppositions that might also influence the subsequent opposition outcomes. Unobservable factors affecting the likelihood of opposition may also affect the probability of specific outcomes, which would generate a bias in our estimated coefficients. This sample selection problem will be the object of future research.

## CRediT author statement

**Lorena M. D'Agostino:** Conceptualization, Methodology, Writing-Original draft. **Lorenzo Tiraboschi**: Data Curation, Methodology, Writing-Original draft. **Salvatore Torrisi:** Conceptualization, Methodology, Writing-Original draft, Supervision.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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**Lorena Maria D'Agostino** is Assistant Professor of Management at the Department of Economics, Management and Statistics, University of Milano-Bicocca, Italy.

She was a post-doc researcher at the Department of Economics and Management, University of Trento, Italy (2017–2019), at the University of Barcelona, Spain (2015–2016) and at the University of Catania, Italy (2012–2014).

She received a Ph.D. in Economics at Marche Polytechnic University, Italy, in 2011. She took an MSc in Industry and Innovation Analysis at SPRU, University of Sussex, Brighton, UK. She graduated from the University of Catania, Italy.

Her current research interests are: green innovation, trademarks, crowdfunding.

**Lorenzo Tiraboschi** received his Master of Science's degree in Marketing and Global Markets in 2020 from the University of Milano-Bicocca, and he has been working there as part of the Research Valorisation Sector since 2021.

**Salvatore Torrisi** is Professor of Strategic Management at the Department of Economics, Management and Statistics (DEMS) of the University of Milano-Bicocca (Italy) where he coordinates the Management Division. He serves as Vice-Rector for Research Valorisation and Technology Transfer of the University of Milano-Bicocca. His research focuses on the economics and management of innovation, competitive strategy, technology transfer and entrepreneurship, strategic management of IP, digital technology and organizational change. He is affiliate to ICRIOS-Bocconi University, CefES-DEMS and member of the European Policy for Intellectual Property Association (EPIP). He is associate editor of the Journal of Industrial and Business Economics and serves as a member of the Editorial Board of the European Management Review. He graduated from Bocconi University (Major: Economics) and obtained a PhD from the Science Policy Research Unit (SPRU), University of Sussex in the UK.