

# Chapter I: Introduction

## 1. *The Underlying Problem*

In a recent patent infringement case between Servier and Apotex, courts in the UK were asked to look into the validity of a pharmaceutical patent that claimed a particular crystalline form of a compound called perindopril. Perindopril is a pharmaceutical compound essentially used to treat hypertension. Its preparation and use had been disclosed in a prior patent. The patent in the referred case, however, claimed a specific crystalline form of a specific salt of this compound, ie the alpha crystalline form of the tert-butylamine salt of perindopril.<sup>1</sup> The High Court found this patent to be invalid for lack of novelty and obviousness. According to the findings of the High Court, the patentee had applied for this patent aware that any known process for producing perindopril would have resulted in the object protected by the new patent. The court further explained that the invalidity of the patent could not be expected to be spotted by the patent office at the examination stage, as some experimental evidence would have been required. The Court of Appeals confirmed the decision of the High Court.

Although these findings have been called into question by the General Court and the invalidity of the patent is in fact far from clear,<sup>2</sup> the judgment of the Court of Appeals, given by LJ Jacob, made in passing a handful of interesting remarks which deserve closer scrutiny.

In the first place, the judgment showed concern about the existence of ‘specious’ patents<sup>3</sup> and stated that ‘[t]he only solution to this type of undesirable patent is a rapid and efficient method for obtaining its revocation’, so that ‘it can be got rid of before it does too much harm to the public

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1 *Les Laboratoires Servier v Apotex Inc* [2008] EWCA Civ 445.

2 Case T-691/14 *Servier v. Commission* (GC, 12 December 2018, ECLI:EU:T:2018:922). Indeed, when assessing a settlement agreement between Servier and Krka, the GC clearly stated that both parties had good reasons to believe that the patent was in fact valid (paras 1147-1205). For a closer analysis of the Servier case, see Joseph Straus, ‘Can Antitrust Adequately Assess Patent Settlement Agreements Disconnected from Patent Law Relevant Facts? The Servier Case – Its Public Perception and its Underlying Facts’ (2016) 38 EIPR 533.

3 *Les Laboratoires Servier v Apotex Inc* (n 1) [9]. The court stated in this regard that it is ‘the sort of patent which can give the patent system a bad name.’

interest.<sup>4</sup> At the most, continued the decision, courts could award costs ‘if the patent is defended unreasonably.’<sup>5</sup>

Secondly, the Court of Appeals highlighted that competition law could hypothetically provide an additional remedy against this kind of patents, though it lamented that this area of law ‘thus far has had nothing or virtually nothing to say about unmeritorious patents.’<sup>6</sup>

As mentioned above, the ‘unmeritorious’ nature of Servier’s patent is in fact far from certain.<sup>7</sup> Yet regardless of the merits of that particular case, into which it is not necessary to delve for the purposes of this work, the observations of the Court of Appeals prompt two general and far-reaching questions which do not typically loom among European courts. In the first place, it raises the question of the available remedies under patent law, either *de lege lata* or *de lege ferenda*, for countering situations involving deceptive or in some other way undesirable conducts before the patent office. Is it true, in this regard, that the only solution for patent law is to have those patents promptly revoked—and perhaps award legal costs? Secondly, but no less important, it puts a question mark over the role that competition law could play in addressing conducts taking place before the patent office. The judgment insinuates that this field of law could indeed provide an alternative solution against dishonest strategies, though it seems to bay for clearer standards on the matter.

## 2. *Deceptive Behaviour in Patent Procedures and Available Remedies under Patent Law*

On the first aspect, and moving on from the particularities of the English lawsuit to the more general questions that it entails, it should be noted at the outset that the current legal situation in most EU Member States does not differ much from the one described by the UK Court of Appeals. Indeed, under the existing patent and procedural laws in these jurisdictions, if an undertaking prosecutes a patent application without good faith or resorts to deceptive manoeuvres, neither the patent offices nor the courts dispose of meaningful remedies other than the rejection of the patent application—or, if granted, its subsequent invalidation—and the award of legal

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4 *ibid.*

5 *ibid* [10].

6 *ibid.*

7 In fact, the fraudulent nature of the patent discussed in that case was later called into question by the General Court. See text in n 2.

costs. In exceptional circumstances, disciplinary sanctions may also come into play, but probably not much more.

US courts and legislature, in their turn, have historically adopted a completely different approach. On the one hand, they seem to expect from patent applicants a much more cooperative role during the examination procedure by imposing upon them a strict duty of candour. This burden includes, *inter alia*, the duty to disclose relevant prior art information of which applicants are aware and which they believe might be relevant for the examination of the patent application. On the other hand, failure from the patent applicants to comply with such stringent duties can have devastating consequences during litigation, as courts may find the patent unenforceable on the basis of inequitable conduct.

The inequitable conduct doctrine, which stems from the long-established doctrine of unclean hands, is a rather unique feature of the American patent litigation system and has been developed throughout decades of case law. Over time, it has become a recurrent component of patent infringement suits and also an object of fierce criticism for its wide scope and for increasing the complexity and costs of litigation. It has even been labelled an ‘absolute plague’<sup>8</sup> due to the frequency with which it is unsuccessfully invoked. Be that as it may, few courts or scholars dare to advocate for its complete eradication, most of them rather suggesting amendments to reduce its negative effects or a revamp into an economic tool for attaining optimal information levels at the patent office.

In this light, it seems worth considering whether any of those features present under US patent law deserve consideration by European law—be that the EPO, the EU or the national laws of any of their Member States. This would involve asking, in the first place, whether it would be advisable to widen the range of duties imposed upon patent applicants, eg in order to collect material information on patentability. Secondly, if the patent is ultimately granted, one might wonder whether the hypothetical bad faith of a patent applicant before the patent office should become a relevant issue during patent litigation and, in that case, whether it in fact calls for a distinct set of remedies.

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8 *Burlington Industries Inc v Dayco Corp* 849 F 2d 1418, 1422 (Fed Cir 1988).

3. *The Patenting Procedure under the Spotlight of Competition Law. Yet another Angle for the IP v Competition Law Debate*

Irrespective of the way in which patent law regulates the patenting procedure and the extent to which patent courts are entitled to take it into account during litigation, the question also arises whether the behaviour of a patent applicant before the patent office can constitute a relevant conduct from a competition law standpoint. Can the deceitful procurement of a patent configure a case of abuse of a dominant position (within the terms of EU law) or monopolisation (in the terms of US antitrust law)?

If one looks into the concerns that are commonly studied by European courts and scholars, it may be noticed that the question of deceptive conduct before the patent office has not traditionally occupied a central place among the general debate on intellectual property and competition. The question, however, seems to have recently gained more attention and certainly offers another interesting angle from where to explore the general interaction between these two areas of law.

It should be noted that, because of their very nature, every patent—regardless of how it has been obtained—is theoretically capable of imposing restrictions upon competitors. In fact, under general conditions, this constitutes one of the distinctive aspects of the patent system, as it encourages firms to innovate with the perspective that they will later enjoy exclusive rights over the accomplished inventions. Furthermore, because patents also incentivise competition in innovation, they also constitute a valuable tool from a competition law standpoint. However, in the hypothetical case where a patent applicant resorts to deceptive strategies to obtain a patent, the fundamental premises underlying the normal equilibrium between intellectual property and competition are disrupted and the intervention of competition law may thus be justified.

The *Servier v Apotex* decision cited above regretted that competition law had virtually nothing to say on this particular question. Since then, however, the CJEU has passed its seminal *AstraZeneca* judgment which dealt precisely with conducts taking place before a patent office.<sup>9</sup> While it is true that *AstraZeneca* concerned a very specific set of facts, essentially related to SPCs and marketing authorisations for pharmaceutical products, the decision unquestionably sheds some light on the problem and confirms that

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9 Case C-457/10 P *AstraZeneca v Commission* (CJEU, 6 December 2012, ECLI:EU:C:2012:770).

the way in which an undertaking conducts its patent application can be a target for competition law scrutiny.

On the other side of the Atlantic, a similar question was posited to the US Supreme Court several decades ago in the *Walker Process* case<sup>10</sup> and since then has been on the table in several court judgments. As a matter of fact, it is a defence not seldom raised by defendants in the course of patent infringement suits. Although those pleas very rarely emerge victorious, US courts broadly recognise that these conducts can be a source for antitrust concern. The standards employed by most of them, though, do not entirely coincide with the CJEU's reading in *AstraZeneca* and their approach tends to focus on the enforcement of the patents obtained through fraudulent means rather than on the fraudulent conduct and following grant of the patent itself.

The differences between both jurisdictions may well originate from divergent underlying approaches, but also from historical circumstances, differences in the legal systems and from nuances in the language of the relevant legal provisions. In any case, it would be important to determine how competition law ought to tackle this kind of behaviour by identifying the appropriate theory of harm and, on that basis, develop corresponding standards for its assessment—logically without forgetting that the particularities of each jurisdiction's legal system may ultimately call for different antidotes.

#### 4. Scope and Structure of this Work

In the light of the range of interrogations prompted along the preceding paragraphs, the purpose of this work is broken down into two essential research questions. In the first place, and based on the US experience with a strict duty of candour and a vast application of the inequitable conduct doctrine, this project seeks to determine whether there are any lessons to be learnt for Europe—or any other jurisdiction with similar legal system—on these particular aspects. More specifically, it explores (i) whether it would be advisable to impose stricter duties upon patent applicants, eg by demanding from them the disclosure of relevant prior art, and (ii) regardless of the extent of those duties, whether it would be sensible for

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10 *Walker Process Equipment Inc v Food Machinery & Chemical Corp* 382 US 172 (1965).

courts to take into account the hypothetical bad faith of a patent applicant as an autonomous defence during infringement proceedings.

In the second place, but certainly no less important, this project attempts to determine how competition law should apply vis-à-vis scenarios involving deceptive conducts before a patent office. The decisions rendered in the US and the EU certainly provide valuable insights, yet—for different reasons—the theoretical criteria underpinning those judgments are at times ambiguous or imprecise. The aim is, hence, to identify the theory of harm underlying these abuses and, from there, understand how EU and US competition rules may be applied within this particular context.

Towards that end, this work is divided into two basic parts. The first part, which is aimed at exploring the first set of questions, comprises two chapters. Initially, in Chapter II, it provides a brief description of the patenting procedure and of the different steps and requirements that patent applicants must follow, both in the US and in Europe, in order to obtain a patent. Next, Chapter III grapples with the question of the behavioural duties of patent applicants by describing the main features of US patent law's duty of candour and inequitable conduct doctrine and comparing them with the situation in Europe. By way of conclusion, the chapter examines the advantages and drawbacks of both systems and balances whether any of the elements present under US law could or should be transplanted to Europe.

The second part of this work deals with the behaviour of patent applicants from a competition law angle. For this purpose, Chapter IV first briefly introduces the fundamental aims and components of competition law, with a logical emphasis on unilateral behaviours. Later, Chapter V succinctly explains the general interaction between intellectual property rights and competition and comprehensively dissects the existing case law in the EU and in the US on the competitive concerns that may be raised against fraudulently obtained patents. Finally, under Chapter VI, the appropriate theory of harm is explored and basic, across-the-board standards for analysis are sought.