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Pharmaceutical Sector: Less  
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# European Commission Enforcement in the Pharmaceutical Sector: Less Than Expected? The Boehringer Case Closure Suggests As Much

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## I. INTRODUCTION

On July 6, 2011, the European Commission (“Commission”) closed the case file in its *Boehringer/Almirall* investigation. It did so without a formal decision, without formal remedies, and without imposing a fine. There is nothing necessarily remarkable about that. Sometimes an investigation simply reveals that there is no case to answer and the file must be closed. But here, something more interesting seems to have been going on. In effect, the Commission reached an informal settlement with Boehringer involving no penalty. In context, that was a curious decision: this was the first definitive enforcement action (albeit informal) taken by the Commission in the wake of the Pharmaceutical Sector Inquiry (“Sector Inquiry”). That suggests something significant about the likely extent of the Commission’s enforcement of EU antitrust rules in the pharmaceutical sector. Teasing out what requires a more detailed look at the underlying facts and the overall context.

## II. THE COMMISSION INVESTIGATION AND THE CASE CLOSURE DECISION

The Commission’s investigation dated back to February 2007. It therefore predated the Sector Inquiry. However, in 2009, following the conclusion of the Sector Inquiry, the investigation had been “relaunched.”<sup>2</sup>

Almirall had submitted a complaint to the Commission alleging that its German competitor Boehringer had misused the patent system by filing for “unmeritorious patents,” covering treatments chronic obstructive pulmonary disease (“COPD”), which had the effect of blocking or seriously delaying Almirall’s market entry.<sup>3</sup> As set out below, this alleged behavior fell squarely within the key areas of concern identified in the course of the Sector Inquiry.<sup>4</sup> Indeed, it seems likely to have been the reason for relaunching the investigation following the Sector Inquiry.

In the press release announcing its case closure, the Commission made it clear that the decision was taken only after—at the urging of the Commission—the parties had settled their dispute. Under the settlement, Boehringer agreed to “remove alleged blocking positions” and “lift

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<sup>2</sup> Commission Press Release IP/11/842, *Commission welcomes improved market entry for lung disease treatments*, (July 6, 2007).

<sup>3</sup> *Id.*

<sup>4</sup> See, eg, Commission Communication, Executive Summary of the Pharmaceutical Sector Inquiry Report, 8, p. 19 (July 2009).

the obstacles to the launch of Almirall's products."<sup>5</sup> The Commission explained the importance of this settlement as follows:

As Boehringer agreed to remove the alleged blocking position, this lifts the obstacles to the launch of Almirall's products and the Commission no longer needs to pursue the case.<sup>6</sup>

The implication appears to be that Boehringer had some case to answer, but the Commission chose not to pursue that case given the settlement.

### III. THE CONTEXT

From the start, the Sector Inquiry was an unusually aggressive affair. It opened, in January 2008, with an unprecedented series of simultaneous dawn raids. At the time of the Inquiry's interim report ten months later, Commission officials announced they had identified a "tool-box" of unilateral practices allegedly used by pharmaceutical patent holders to delay the market entry of generic products<sup>7</sup> and the then Competition Commissioner Neelie Kroes told the world that:

"Competition in this industry does not work as well as it should."<sup>8</sup>

The final report in July 2009 identified two classes of concerns. First were concerns regarding a series of practices on the part of patent holders allegedly designed to keep competitors out of the market. These included the tool-box practices directed against generic producers and "defensive" or "blocking" patents directed against other innovators.<sup>9</sup> These unilateral practices would be pursued as abuses of dominance under Article 102 TFEU. Second, there were concerns regarding certain categories of settlements agreement in patent litigation, particularly so-called "reverse payment" or "pay-for-delay" settlements. These could be pursued under Article 101 TFEU.

In the final report, the Commission promised to subject the sector to "increased scrutiny under the EC competition law" and warned, "[f]irst enforcement action is already underway."<sup>10</sup>

A year later, on July 1, 2010, the Commission's ability to pursue the first set of concerns under Art. 102 received a significant boost with the General Court judgment effectively upholding the Commission's 2005 *AstraZeneca* decision.<sup>11</sup> *AstraZeneca* was the first abuse of dominance decision ever taken by the Commission in the pharmaceuticals sector. (Indeed, to date, it remains the only such decision.) The General Court upheld both the approach the Commission had taken to market definition in the pharmaceutical sector and, as importantly in the context of the Sector Inquiry, the two abuse of dominance findings in the case.

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<sup>5</sup> Commission Press Release IP/11/842, *supra*.

<sup>6</sup> *Id.*

<sup>7</sup> Preliminary Report, Pharmaceutical Sector Inquiry, (November 28, 2008).

<sup>8</sup> Neelie Kroes, Speech/08/659, *Preliminary report of sector inquiry into pharmaceuticals*, (November 28, 2008).

<sup>9</sup> Final Report, Pharmaceutical Sector Inquiry, (July 8, 2009).

<sup>10</sup> Commission Communication, Executive Summary of the Pharmaceutical Sector Inquiry Report, p. 27 (July 8, 2009).

<sup>11</sup> Case T-321/05 *AstraZeneca v Commission*, [2010] ECR II-2805.

In general terms, these abuses may be summarized as (i) obtaining exclusive IP rights by deception and (ii) misusing regulatory procedures for the purposes of excluding competitors from the market. These theories are the most likely basis for pursuing the potential abuses identified in the Sector Inquiry.<sup>12</sup> Both theories of abuse were novel and many—including perhaps the Commission—had felt there was a real risk that they would not be upheld by the General Court. The case remains under appeal before the European Court of Justice (“ECJ”), so the Commission’s decision and approach may yet be set aside, but the risk has unquestionably declined. Indeed, the Advocate General recently issued an Opinion recommending that AstraZeneca’s appeal be rejected so the indications are that the decision will stand.<sup>13</sup>

At the time of the General Court judgment, the only publicly announced follow-up investigation from the Sector Inquiry was that relating to Servier, which appears to be primarily a patent settlement case.<sup>14</sup> There was speculation that the Commission was waiting for the General Court judgment before progressing other investigations, particularly abuse of dominance cases. However, if the judgment led to increased enforcement action, there was no external sign that this was the case.

It was against this background of expectations raised by the Sector Inquiry, recently obtained judicial support for its abuse of dominance theories, and limited public enforcement action that the Commission decided to announce that its first intervention in the pharmaceutical sector would be a case closure without fines.

#### IV. THE UNDERLYING DISPUTE

Many of the key facts in relation to the underlying dispute between Almirall and Boehringer and the Commission investigation are conveniently set out in a 2009 judgment of the English High Court in relation to Almirall’s challenge to the validity of the relevant Boehringer patents.<sup>15</sup> In 2001, Almirall obtained patent protection in relation to Aclidinium, an anticholinergic it had developed. Anticholinergics are a class of drugs used in the treatment of COPD and other lung diseases.

For mild, stable COPD, the first line treatments are either anticholinergics or another class of drugs known as betamimetics (or “ $\beta$ 2 agonists”). In moderate to severe cases, the two agents are used together in combination. Such combination products have been on the market since the 1990s.

In May 2003, two posters presenting preliminary clinical work in relation to Aclidinium, together with a representation of its chemical structure, were displayed at the American Thoracic Society conference in Seattle. A Boehringer scientist attending the conference took photographs of the posters, which were then sent to Boehringer’s International Project Management team in Germany for a “Competitive Assessment Update.”

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<sup>12</sup> Sean-Paul Brankin, *The AstraZeneca Judgment: A Green Light for Further Action on Pharma and IP*, 9(2)CPI ANTITRUST CHRON. (September 30, 2010).

<sup>13</sup> Case C-457/10 P *AstraZeneca v Commission*, Opinion of Advocate General Mazak, (May 15, 2012).

<sup>14</sup> Sean-Paul Brankin, *The Pharmaceuticals Sector Inquiry: Anything to Report?*, GLOBAL COMPETITION POLICY (GCP) (November 2008).

<sup>15</sup> *Laboratorios Almirall v Boehringer Ingelheim International*, [2009] EWHC 102 (Pat).

Boehringer was strongly represented in the field of anticholinergics in 2003 with a number of what the English Court described as “classic offerings,” including Atrovent, Oxivent, and Spiriva. By 2011, Spiriva had become a blockbuster drug: in 2010, it achieved a worldwide turnover of almost EUR 3 billion.<sup>16</sup> Back in 2002, Boehringer had launched a combination treatment for COPD called Combivent. Combivent comprised an anticholinergic combined with a  $\beta$ 2 agonist. Combivent rapidly became a market-leading product. It remained the market leader in the treatment of COPD in 2011.<sup>17</sup>

Less than three months after the Seattle conference, on July 29, 2003, Boehringer filed three patent applications in relation to various combinations of Aclidinium and a range of other drugs. The third patent covered combinations of Aclidinium and  $\beta$ 2 agonists for the treatment of COPD. The applications stated that:

Surprisingly, an unexpectedly beneficial therapeutic effect can be observed in the treatment of inflammatory and/or obstructive diseases of the respiratory tract if the anticholinergic [Aclidinium] is used with one or more betamimetics.

The patent application gave no further information as to the nature of the unexpectedly beneficial therapeutic effects that had been observed. There seems to have been a simple reason for this: between taking the photographs of Almirall’s molecule and making its patent application, Boehringer appears not to have conducted a single relevant experiment.

In light of this history, the English judge found, in relation to Boehringer’s claim that unexpectedly beneficial effects could be “observed,” that:

“This statement is therefore false ... no one ever observed anything relevant.”

Nor was this false statement in the patent application incidental. It was integral to the application. The use of combination therapies comprising an anticholinergic and a  $\beta$ 2 agonists were “an integral part of the common general knowledge” at the time of Boehringer’s application. In fact, combination therapies were already a recommended treatment for severe COPD in leading textbooks and under the guidelines issued by both the British Thoracic Society and the U.S. National Institute of Health. Therefore, without some additional “unexpectedly beneficial therapeutic effect” having been observed, there would be no inventive step and the patent would be void for obviousness. Accordingly, having found that no such observation had been (or could have been) made, the English Court revoked Boehringer’s U.K. patent.

## V. A STRONG PRIMA FACIE CASE OF ANTITRUST INFRINGEMENT

On the basis of the facts outlined above, the case against Boehringer would appear *prima facie* to be a strong one. Indeed, on its face, it is not easy to imagine a more attractive *prima facie* fact pattern for the Commission. The Commission could apparently show that:

- for at least one class of patients—those with severe COPD—combination therapies were the recommended treatment;

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<sup>16</sup> Commission Press Release IP/11/842, *supra*.

<sup>17</sup> *Id.*

- Boehringer had the market leading combination treatment (Combivent) and a blockbuster anticholinergic (Spiriva);
- Boehringer had made material statements in a patent application that were not only misleading but found by an independent judge to be false (and which Boehringer must have known to be false); and
- as a result, Boehringer obtained at least one patent covering combination therapies involving the patented active substance of its competitor Almirall.

To establish an infringement of Art. 102, the Commission would need to show both dominance and abuse. Following *AstraZeneca*, abuse would not seem difficult: Boehringer had obtained exclusive IP rights as a result of statements that, according to the English Court, were false and misleading. As regards dominance, and again following *AstraZeneca*, there would appear to be a separate market for combination therapies on the basis that there is a defined patient group for whom this is the preferred therapy. In that market, Boehringer had the “market leading” product at the time of its patent application and remains the “market leader” in 2011. It also had a series of “classic offers”, including the blockbuster Spiriva, in the class of drugs (anticholinergics) to which the Almirall molecule covered by its patent belonged.

In fact, the Commission appears to have been confident of the position in relation to dominance. It has stated that, when it relaunched its investigation of Almirall’s complaint in 2009, the “main focus” of its investigation was not dominance but:

whether Boehringer had filed patent applications and had obtained patents by providing misleading information to the EPO.<sup>18</sup>

## VI. SO WHY DID THE COMMISSION CLOSE ITS FILE?

To recap, the Commission found itself, in mid-2011, two years on from an aggressive and high profile Sector Inquiry in which it had promised enforcement action, with a very strong *prima facie* case in one of its priority areas. It had (and has) yet to establish a strong enforcement record in this area. Indeed it had no established follow-up precedents from the Sector Inquiry. It did have one related precedent on its books (*AstraZeneca*) and that had recently been upheld by the General Court.

Against that background, it chose to adopt what is, at best, a weak precedent: a simple file closure without any formal decision (not even a commitments decision) and without the imposition of even a nominal fine. Admittedly, it had brokered a settlement between the parties. But this suggests the threat to an undertaking that risks infringing EU competition law in this way is that it has to allow access under its (potentially invalid) patents eight years after applying for them. In these circumstances, why would Boehringer—or any other undertaking in a similar position—not behave as it had in this case all over again?

Why would the Commission accept such an outcome? There are two obvious possibilities. First, appearances to the contrary, the Commission may not have had a strong case on infringement. Second, the Commission may genuinely have taken the view that the benefits of

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<sup>18</sup> Commission Press Release IP/11/842, *supra*.

a settlement outweighed the costs of a less than ideal outcome from an antitrust perspective. Either possibility has interesting implications.

If the Commission was worried about the strength of its case, then the concerns would presumably relate either to proof of abuse or proof of dominance. Unless the ECJ decides to depart radically from the position of both the General Court and its own Advocate General and overturn *AstraZeneca*, the case on abuse seems strong. Certainly, if Boehringer's actions do not constitute abuse, examples of abusive patenting are likely to be few and far between.

Further, the case on dominance also looks strong. Boehringer was a long-time market leader in what appears to be a relevant market, had a related blockbuster drug, and held a blocking patent. Again, if dominance cannot be established on these facts, the implication would appear to be that dominance in the pharmaceutical sector is far from straightforward to prove. Either way, if this was not a strong case then the implication appears to be that the enforcement of EU competition law in the pharmaceutical sector will not be as extensive as some might have feared following the Sector Inquiry.

Alternatively, the Commission may have foregone a strong case in order to achieve a beneficial settlement. Certainly the Commission press release in relation to the case states:

Boehringer had appealed [the 2010 EPO decision revoking its patent] to the next EPO instance, and the effect of the appeal was to keep the contested patent in force until the appeal had been decided. Some years ago Boehringer had also filed so called divisional patent applications that were based on the main patent application, which were dormant, but could have been reactivated and thus prolong the patent dispute even after the EPO annulled the contested patent.<sup>19</sup>

The problem with this explanation is that it undermines the Commission's position in relation to the second set of issues highlighted as a priority in the context of the Sector Inquiry, i.e. patent settlements. If the Commission is itself content to sacrifice strict enforcement of the antitrust rules in order to achieve a settlement that results in greater short-term competition, how can it credibly pursue so called "reverse payment" or "pay-for-delay" patent settlements that involve exactly the same trade-off? Certainly, it seems inconsistent with subjecting such settlements to a presumption of illegality, as advocated by the U.S. Federal Trade Commission and discussed in the Sector Inquiry report.

In fact, the most likely explanation for the Commission's behavior is that both explanations apply, at least to some extent. If so, it seems that enforcement of the EU competition rules by the Commission may be less aggressive in both its priority areas—abuses of dominance and settlement agreements—than might have initially been feared following the Sector Inquiry.

## VII. CONCLUSIONS

The *Boehringer/Almirall* decision is of course only one case closure. Future enforcement action by the Commission may clarify the position. However, the following conclusions appear justified:

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<sup>19</sup> Commission Press Release IP/11/842, *supra*.

First, enforcement action by the Commission in relation to abuses of dominance in the pharmaceutical sector seems likely to be less extensive than might reasonably have been expected in the immediate wake of the Sector Inquiry. This does not mean that the Commission has not lost interest in the sector. The specialist unit (E1) set up within DG Comp following the Sector Inquiry remains in place and its officials remain committed and engaged. Nonetheless, it seems reasonable to adjust risk assessments downwards.

Second, the Commission appears to be open to informal settlements in appropriate cases. Undertakings under investigation—and those contemplating behavior that might later be challenged—should give thought to what concessions they might offer in exchange for case closure.

Finally, one clear outcome of the case is that the Commission has publicly acknowledged the public interest value of patent settlement agreements can have in achieving early market entry. This is in clear tension with its position in relation to “reverse payment” or “pay-for-delay” settlements, except perhaps in the most egregious cases, and difficult to reconcile with any presumption that such settlements are generally unlawful.