Select Competition Issues Arising from Changes in the Distribution of Pharmaceutical Products in South Africa

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ABSTRACT

This paper considers the competition impact of recent changes in the modes of pharmaceutical distribution. It contains a brief look at the nature of these changes and raises a selection of key issues that the industrial organisation and competition policy literature offers insight into, demonstrating the intricacies of any assessment of the competition impact of distribution arrangements of this nature.
1. INTRODUCTION

Significant changes have taken place in the distribution stage of the pharmaceutical supply chain in South Africa during the past decade. These have led to a series of complaints and applications for interim relief to the competition authorities. The Competition Tribunal has delivered some judgements that have been in favour of the pharmaceutical manufacturers and others in favour of the wholesalers.

The purpose of the paper is to reflect on the changes that have taken place in the distribution stage of the pharmaceutical supply chain, and to flag a selection of issues that arise in an assessment of the competition impact of these changes. As a case is currently in process at the Tribunal, it is important to skirt *sub judice* territory, and therefore this paper does not present a complete review of Tribunal decisions.

This paper starts with a brief review of recent developments in the pharmaceutical industry in South Africa. The changes within the distribution stage of the supply chain are particularly pertinent in the context of the series of competition cases that have been decided by the Competition Tribunal since 1993. We then flag select issues that are relevant to a consideration of the competition impact of the joint exclusive distribution ventures that have been established by groups of pharmaceutical manufacturers or the exclusive dealing arrangements that manufacturers have entered into with distribution enterprises. This exercise emphasises the complexity of such assessments, to which the ongoing rounds of cases before the Tribunal are also testimony.

2. DEVELOPMENTS IN THE SOUTH AFRICAN PHARMACEUTICAL INDUSTRY

Until 1993 the South African pharmaceutical supply chain\(^1\) followed the traditional and still predominant international model.\(^2\) This model is presented in Figure 1. Multinational pharmaceutical companies feature prominently in the production stage of the supply chain. Distribution of pharmaceutical products is by independent wholesalers who buy stock for their own account from manufacturers and on-sell to retailers. Wholesale distribution of pharmaceutical products is done either by full-line or short-line wholesalers. Full-line wholesalers distribute the full range of available pharmaceutical products, and short-line wholesalers trade in a selection of products only.

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\(^1\) Focus in this paper is on the private segment of the total health care market, where delivery is in private hands.

\(^2\) IMS Health: World Review and Pharmaceutical Distribution Data.
Wholesalers cover their costs and make a profit based on the difference between the price at which they buy from the manufacturers and the price at which they on-sell to the retail trade. The price differential takes the form of a discount (historically 17.5%) granted by manufacturers to wholesalers off the list price. Wholesalers pass on a significant portion of this discount, as is demonstrated by reported margins, to retailers as they compete for market share. Retailers on-sell to consumers in the final stage of the supply chain. These are pharmacies (mostly individually-owned, although several retail chains do exist) and, since 1984, dispensing doctors.

The pharmaceutical supply chain is usually described as a producer-driven one, despite the specific consumer demand characteristics, especially in the private segment of the health care market. This description reflects the significant market presence and influence of the large multinational pharmaceutical producers in the health care market.

The international market for the production of pharmaceutical products has seen several waves of merger and acquisition activity in recent years, as pharmaceutical firms have tried to negotiate the myriad of changes, not only in pharmaceutical research and manufacture, but also in the regulatory environment and in the demand for pharmaceutical products. The South African pharmaceutical industry has reflected international trends, a selection of which is presented here.

2.1 Changes in the Regulatory Environment and in Consumer Demand

The private segment of the market for pharmaceutical products (which is the focus of this paper) is characterised by highly inelastic demand. This results from the ‘must have’ nature of ethical or prescription drugs, which is supported by the power of the doctor’s pen. The inelasticity is further enhanced by extensive membership of medical aid schemes. Since the cost of such drugs is veiled by the medical aid scheme, it does not directly confront the consumer, with the result that price sensitivity is muted.

This inelasticity may, however, be changing for a number of reasons, some of which relate to changes in the regulatory environment. The amended *Medicines and Related Substances Control Act*, No. 101 of 1965, proposes mandatory generic substitution. A pharmacist will be required to inform “all members of the public who visit his or her pharmacy with a prescription for dispensing, of the benefits of the substitution for a branded medicine of an interchangeable multi-source medicine” (s22F), and to dispense “an interchangeable multi-source medicine instead of the medicine
prescribed...unless expressly forbidden by the patient to do so” (*Ibid.*). This, along with the provision to facilitate parallel imports (s15C (b)), is likely to increase the elasticity of demand for ethical or prescription drugs.

Another significant challenge for producers is implicit in the proposed single exit pricing provided for in s22G, 3(a). This means that a single price will be prescribed for manufacturers when they sell to anyone other than the state. The differential system of discounts operated by some manufacturers and wholesalers will no longer be permissible.

The *Medical Schemes Act*, No. 131 of 1998 (effective from 1 January 2000), sets out the conditions applicable to the admission of an individual to a medical aid scheme (s29 (n)). These conditions, which provide for the determination of contributions on the basis of income or the number of dependants or both, do not take into account age, gender, past or present state of health of potential members, or the frequency of use of health services. The scope and level of minimum benefits may be proscribed, and adjustments to the scale and scope of benefits may be made within certain prescribed parameters.

At first glance, it would appear that the greater access to medical aid coverage would reduce the elasticity of demand. However, after the first year of operation under the new Act, a number of medical aid schemes announced changes to their benefit options; in particular, the day-to-day coverage was reduced. This effectively means that the benefit ceiling is reduced, and the member is then responsible for costs of medical treatment and prescribed drugs incurred beyond that ceiling. This is likely to raise the elasticity of demand. The net effect of these changes, greater accessibility to medical aid coverage combined with less effective cover, is what matters.

Even in view of these changes, it is perhaps still true to say that the demand for ethical or prescription drugs is relatively inelastic. The elasticity may, however, be higher than it used to be as a result of the changes. Manufacturers can be expected (rationally) to consider their market positions very carefully with respect to this set of changing conditions.

### 2.2 Changes in Pharmaceutical Distribution

Changes in the wholesale distribution of pharmaceutical products\(^3\) have led to a series of applications for interim relief and complaints to the Competition Authorities since 1993. We catalogue very briefly here the changes that have taken place at this stage of the supply chain, with the establishment of three exclusive distribution enterprises.

### 2.3 International Healthcare Distributors

In 1992, a “few like-minded pharmaceutical companies met to discuss the possibility of a distribution venture.”\(^4\) “Four companies, Boehringer Ingelheim, Roche, Bayer and Ciba-Geigy committed to the formation of a common distribution venture”

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\(^3\) The relevant market has been defined, and accepted by the competition authorities in a number of cases, as being the market for the wholesale distribution of pharmaceutical products.

Representatives of the four companies submitted a proposal, (that became International Healthcare Distributors (IHD)) to their principals in Europe and received formal approval in July 1993 from the European head offices. IHD started trading in December 1993. Since then, a number of pharmaceutical manufacturers have joined IHD and it is now jointly owned by eleven multinational manufacturers for whom it distributes pharmaceutical products to the retail trade.  

The entry of IHD (which may be described as a joint, exclusive distribution venture) into the market for the wholesale distribution of pharmaceutical products changed the configuration of the pharmaceutical supply chain by effectively segmenting the market. The establishment of IHD has created a process of partial disintermediation as traditional wholesalers are displaced with respect to the products of those manufacturers that distribute their products through IHD. Wholesalers, either full-line or short-line may still buy the products of these manufacturers through their exclusive distribution agency, but they buy on exactly the same terms as the retailers to whom they on-sell. The discount structure that used to apply to wholesalers (a 17.5% discount) has fallen away. This, the wholesalers have argued (in submissions to the Competition Tribunal in support of applications for Interim Relief), makes their role (ceteris paribus) of suppliers to the retail trade, commercially unviable.

2.4 Kinesis Logistics

In 1998, a second joint exclusive distribution agency was established when five pharmaceutical manufacturers formed an investment company, Synergistic Alliance Investments (SAI). SAI acquired Druggists Distributors (DD), a traditional full-line wholesaler to exclusively distribute the products of the principals and two other manufacturers. DD was converted from a traditional full-line wholesaler to a distribution agency that was to distribute to retail pharmacies, mail order (pharmacy) companies, dispensing doctors, private and public hospitals and clinics, as well as (theoretically) wholesalers. Druggists Distributors currently trades under the style Kinesis Logistics.

2.5 Pharmaceutical Health Distributors

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5 The 11 are: Abbott Laboratories; Aventis; Bayer; Boehringer Ingelheim; Bristol-Myers Squibb; Eli Lilly; MSD; Novartis; Roche; Schering; and Wyeth.
6 It may be that there is a distinction between full-line and short-line wholesalers as regards discount structure – a call to IHD suggests that this distribution agency distinguishes between the two types of wholesalers. It has proven rather difficult to ascertain exactly what the discount structures are as access to pricing information is closely guarded.
7 We do not consider here other services that wholesalers could develop in order to compete with the exclusive distribution agencies.
8 Traditional wholesalers still buy from manufacturers that are not involved in the ‘new’ distribution arrangements on the same terms as before – 17.5% discount.
9 Glaxo Wellcome SA (Pty) Ltd; Pfizer Laboratories (Pty) Ltd; Pharmacare Ltd – now Aspen Pharmacare; SmithKline Beecham Pharmaceuticals (Pty) Ltd; and Warner Lambert SA (Pty) Ltd. Two other manufacturers were also contracted to SAI – Janssen Pharmaceutica (Pty) Ltd and Merck (Pty) Ltd. Merck has since 27 March 2000 used PHD as its sole distribution agency. This arrangement is valid until March 2002.
10 On the same terms as to wholesalers.
As of 25 November 2000, AstraZeneca (AZ) has used Pharmaceutical Health Distributors (PHD), another distribution firm, as its sole distribution agent, on a fee-for-service basis. In terms of the distribution agreement, the warehousing and distribution functions, as well as the generation of orders, credit control and debt management, are provided by PHD until the end of 2002. AZ maintains ownership of stock until sold to a third party.

3. ASSESSMENT OF COMPETITION IMPACT: SELECT ISSUES

The three distribution arrangements, which currently exist alongside the traditional wholesale model, share a number of characteristics, but also differ in some respects. In the case of IHD the arrangement has been characterised as a joint venture. Since the joint venture involves several manufacturers in an exclusive distribution arrangement, there is a vertical relationship between the manufacturers and IHD. This vertical relationship involves *joint ownership* of the distribution enterprise by the manufacturing firms.

Kinesis Logistics, whose holding company SAI is owned by five pharmaceutical manufacturers was, until May 2001, a joint venture like IHD. Unlike IHD, however, SAI also distributed for two manufacturers that were not owners of SAI, as well as for other parties, as indicated above. SAI therefore involved differential modes of vertical integration. It involved joint ownership, as in the IHD scenario but also agency relationships.

The formation of both IHD and SAI involved collective action by several manufacturers. This does not, however, necessarily imply collusion – either tacit or explicit. Both IHD and SAI involve a measure of vertical integration in the sense of the involvement of two successive stages of production in the supply chain. The literature on vertical integration in general (see for example, Perry 1989) and on public policy towards vertical integration, in particular, provides a wealth of evidence, suggesting that in certain cases vertical integration may be benign while in others it may have anti-competitive effects.

The Kinesis relationship took an interesting turn earlier this year. One of the principals, Aspen Pharmacare (the only South African firm participating in this venture), openly expressed dissatisfaction with the Kinesis arrangement. In May of this year, SAI (the holding company of Kinesis Logistics) was sold to Tibbet & Britten SA (Pty) Ltd, a subsidiary of a multinational supply chain management enterprise. In terms of the sale agreement, Tibbett & Britten acquired the holding

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11 It is true that the initial discussions would have involved information sharing, which may be held to have facilitated collusion. This is noteworthy with respect to the distinction between US anti-trust legislation and EU-type competition law. In the US prima facie would be required to prove collusion, this is not necessary in the EU.

12 SA Druggists was party to the Kinesis arrangement. In March 1999 Aspen Pharmacare inherited a contractual obligation from SA Druggists to change its primary distribution channel to Kinesis in terms of agreements concluded by Pharmacare Limited before the acquisition of that company from SA Druggists. Aspen Pharmacare notes in its financial statements for six month period ended 31 December 2000, that the distribution fee to Kinesis ‘gave rise to no commercial benefit’ and that ‘working capital levels were negatively affected’ [www.pharmacare.co.za/showarticle.php?id=108](http://www.pharmacare.co.za/showarticle.php?id=108)
company SAI and would provide (exclusive) distribution services to Aspen Pharmacare and its fellow members of SAI under separate contracts. This new arrangement is best characterised as an exclusive dealing arrangement.\(^{13}\)

The third distribution arrangement, which has become known as the PHD case, adds further interesting variations on the distribution theme. PHD (Pty) Ltd is a logistics company, which in association with other companies, provides distribution, warehousing, debt collection, batch tracking, order processing, picking, packing credit control and debt management to its principals. The associated companies are:

- Kite Logistics (Pty) Ltd, which transports pharmaceutical products to pharmacies and doctors;
- Order Pharm (Pty) Ltd, which processes orders, received from customers (wholesalers and pharmacies);
- Railit Total Transportation (Pty) Ltd which provides distribution and transport services of pharmaceutical products to the government and wholesalers; and
- Recall (Pty) Ltd, which is responsible for debt management on behalf of PHD.

The PHD arrangement may also be characterised as an exclusive dealing arrangement. It’s interesting to note that PHD and Recall are wholly owned subsidiaries of Fuel Logistics Holding Company Limited, which owns a 50% share of Kite. The other 50% shareholder of Kite is IHD!

### 3.1 Competition issues arising from the new distribution arrangements

The complaints and applications for interim relief that have been brought by the traditional wholesalers to the competition authorities have attempted to show that the joint exclusive distribution arrangements constitute restrictive practices, either of a horizontal or vertical nature, or that they involve abuse of a dominant position. These prohibited practices are covered by Chapter 2 of the Competition Act, No. 89 of 1998 (as amended).

In support of their positions, the pharmaceutical manufacturers have advanced a range of pro-competitive arguments, citing efficiency gains, technology gains and the promotion of the public interest as factors motivating the formation of the joint exclusive distribution enterprises, and countering claims of anti-competitive effects resulting from these arrangements. The arguments are not reviewed here.\(^{14}\) Instead, a selection of key competition concerns raised by the joint exclusive distribution arrangements in pharmaceutical distribution will be considered.

#### 3.1.1 Commercial interaction or anti-competitive behaviour

The distinction between commercial, competitive interaction and anti-competitive behaviour is sometimes very difficult to draw. We need to recognise that competitive (commercial) interaction may result in smart moves by firms that may disadvantage

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\(^{13}\) Mathewson and Winter (1987).

\(^{14}\) Glynn (2000) presents a comprehensive catalogue of these.
others, who may be in the same market or in a market related to that of the smart mover. Such competitive interaction need not necessarily raise competition concerns, quite the contrary in fact!

To illustrate this, consider some of the effects that have resulted from the formation of the distribution ventures. If we look at the entire pharmaceutical supply chain, then it becomes clear that, since the introduction of joint exclusive distribution ventures (whether exclusive dealing arrangements or vertical integration arrangements), the distribution of risk and transaction costs of doing business through the supply chain has changed. In the traditional supply chain model, the wholesalers buy stock for their own account from manufacturers and on-sell to retailers. Retailers buy from wholesalers to meet consumer demand (reflecting their pharmacy or medical practice-specific demand profile). Wholesalers offer a flexible delivery service, with multiple deliveries per day, which facilitates minimal inventory holding by the individual pharmacy or medical doctor, thus minimising risk of theft (with implication for insurance costs), mismatches between demand and supply, and also mitigating the costs of high levels of inventory holding (investment in inventory).

Instead of offering this flexible delivery service the new, joint exclusive distribution model provides less frequent deliveries to retailers. IHD does not, for example, guarantee same-day delivery except in exceptional circumstances. This means that retailers have to hold more stock and, with more stock holding comes the associated increase in risk and in other transaction costs of doing business. The key question is whether this raises competition concerns, or whether it merely reflects the outcome of commercial, competitive interaction. From a South African competition policy perspective, we need to reflect on a number of issue, such as:

- **Specific concerns about small and medium-sized firms expressed in the Competition Act**
  These concerns are brought into play when one considers the size distribution of firms through the supply chain. There seems to be a cascading distribution, with larger firms upstream and smaller firms at the retail end of the supply chain.

- **The public interest implications of these changes**
  One of the issues that would be key here is the impact that these arrangements have on the consumer, especially in so far as accessibility, availability and price of prescription drugs are concerned.

3.1.2 Exclusive dealing

A distinctive feature of all the arrangements considered is an *exclusivity clause*, which each manufacturer enters into with the distribution enterprise. In all cases, to our knowledge, the exclusivity clause is time-bound.

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15 Disadvantage is used as a neutral term – not necessarily implying anti-competitive behaviour.

16 Price effects have been considered by the Competition Authorities in various matters, but the evidence is not entirely clear. Causality confusion is frequently a problem in such cases. It is perhaps instructive that the CEO of SAI, on its formation, remarked that price decreases would not necessarily result from the joint exclusive distribution venture. This is merely suggestive, but nonetheless indicative, of the fact that an assessment of efficiency gains needs to go beyond price effect.
Competition and Changes in the Distribution of Pharmaceutical Products

The position of the competition authorities is that exclusivity is not necessarily problematic, but that the joint nature of an arrangement should be examined to determine whether horizontal collusion exists.  

The extensive body of literature on exclusive dealing offers a range of perspectives, some emphasising the potential for efficiency enhancement, specifically in the form of lower prices (Mathewson and Winter, 1987) even when the market is foreclosed to one of the manufacturers in a duopoly model. A contrasting view comes from Krattenmaker and Salop (1986). They argue that exclusionary contracts are frequently designed to raise rivals’ costs and so deter competition. Accordingly, there are situations where exclusive dealing contracts have a purely strategic purpose, with few – if any – compensating efficiencies. These results need to be reflected upon in each specific case.

Another issue that is pertinent to the exclusive dealing arrangement is whether or not the vertical arrangement veils a horizontal relationship between competitors. On this score, the competition authorities have held that evidence of actual collusion is required; mere conjecture, suggestion or facilitating circumstances are insufficient. To date this has not been garnered in any relevant case.

3.1.3 Agency or ownership – does it make a difference?

Does ownership of the distribution venture differ materially from an agency relationship (between manufacturers and the distribution enterprise) from a competition perspective? Neither the presence of ownership nor the presence of an agency relationship is, in itself, sufficient to prove a restrictive practice. The one is merely a weaker form of vertical integration than the other (Case No. 98/IR/Dec00 – Competition Tribunal) and vertical integration may be associated with either pro-competitive or anti-competitive effects.

Inherent in the concept of vertical integration is the elimination of market exchanges, and the substitution with internal exchanges within the boundaries of the firm. Definitional certainties are required when assessing agency as opposed to ownership concerns. It becomes necessary to ask whether the specific exclusive agency agreement eliminates market exchange. We also need to consider the definition of a single economic entity for competition policy purposes (see footnote 20).

An analysis of principal-agent relationships suggests that ownership may indeed reduce transaction costs and lower specific risk, thus producing efficiency gains. It

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17 A game theoretic argument may be considered here – in a Nash Equilibrium, this clause would be superfluous, casting doubt on the purported efficiency support for its inclusion.
18 In Tribunal Case No. 68/IR/Jun00, it is suggested that exclusivity does not necessarily contravene the Competition Act, but that the joint nature of the agreement (joint ownership in the case of IHD) implied horizontal collusion such that interim relief could be granted to the applicants.
19 The transaction cost literature notes a range of efficiency gains associated with vertical integration, e.g. asset specificity (this argument has been put forward by manufacturers as regards investment in distribution infrastructure) and adaptation to uncertainty, risk and complexity (this is relevant in the context of changes such as generic substitution and parallel imports).
20 Effective transfer of information between manufacturer and distributor, is an example.
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may, however, also facilitate collusion. Matters of ownership and control need careful analysis in order to identify any pro-competitive and anti-competitive effects. This analysis should note the conclusions of a series of indistinguishability theorems (is it collusion or is it competition?) in the industrial organisation literature, and their implications for the operation of competition policy.

3.1.4 Impact on the nature and extent of competition

Product brands play a significant role in the market for pharmaceutical products. Patent protection excludes competition for a prescribed period of time, during which the manufacturer reaps monopoly rents. Brands are therefore an important consideration when assessing market power in the pharmaceutical industry.

In an overall assessment of the impact of joint exclusive distribution on competition, two types of competition are relevant: inter-brand and intra-brand competition. As regards intra-brand competition, the impact of the establishment of the distribution enterprises on the sources (availability) of specific drugs is important. Wholesalers have argued (Competition Tribunal Case No. 98/IR/Dec00) that the establishment of exclusive joint distribution enterprises reduces the distribution channel options of the relevant products and that, as a result, intra-brand competition is reduced. This argument is intuitively appealing, but may not stand scrutiny where exclusivity is partial in the sense that it is mediated by a reduced discount structure (down from 17.5% to 11-13%) for wholesalers, as in the case of AstraZeneca (ibid.), as opposed to a complete elimination of the wholesale discount as is the case with IHD. It may be argued that the lower discount still facilitates a distribution role for traditional wholesalers (and an incentive to reduce their costs to enable them to compete on price with the joint exclusive distribution agency, as well as engage in non-price competition). Conclusions therefore hinge on the extent of the discount offered to traditional wholesalers, and in turn their possibilities for lowering costs and engaging in non-price competition.

The extent of inter-brand competition depends on the own price elasticity of demand as well as cross-price elasticities of demand. The availability of substitutes for a particular drug and the prescribing preferences of medical doctors are important considerations (and these will be influenced by generic substitution and parallel imports). Also important is competition among manufacturers within a specific exclusive distribution arrangement (intra-arrangement) and that among manufacturers belonging to different distribution arrangements (inter-arrangement competition). It may be true that competition within an arrangement is subdued by the joint exclusive distribution arrangement, but it is possible that simultaneously, inter-arrangement

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21 It may also be of interest to note the decision of the competition authorities concerning ‘the single economic entity’ in the Distillers case, in this regard. See the Competition Tribunal website for further details.

22 Unless competition authorities have access to an implausible amount of information, it is impossible to tell, for example if simultaneous price movements are the result of collusion or simply reactions to exogenous demand shifts. A submission to the Tribunal (Case No. 53/IR/Apr00) argued that the fact that SAI principals offer different discount structures, implies that they are not colluding. The indistinguishability argument puts paid to that submission.

23 Eli Lilly produces Prozac, which came off patent in August. During the next month, sales of Prozac fell by 80%!
competition among competing brands may increase. The analysis has, of course, to be done for specific therapeutic categories to draw sensible conclusions. The question then is: On balance, what is the effect on inter-brand competition?

An overall assessment of the competition impact should balance considerations relevant to both intra-brand and inter-brand competition before drawing any conclusions.

4. CONCLUSION

The changes in modes of pharmaceutical distribution that have developed during the past decade have altered the configuration of the South African pharmaceutical supply chain in a number of respects. These changes, which have been motivated and initiated by groups of pharmaceutical manufacturers, have led to a series of hotly contested competition cases posed both as applications for interim relief and as complaints. Some cases have found for the wholesalers, while others have found for manufacturers and/or their exclusive distribution ventures. These disparate outcomes do not point to confusion on the part of the competition authorities, but rather indicate the intricacies of any assessment of the competition impact of these distribution arrangements.

This paper has sought to raise a selection of key issues that the industrial organisation and competition policy literature offers insight into. As we’ve seen the insights do not provide unambiguous guidance for an assessment of the competition impact of the joint exclusive distribution activities. This is where the interface between law and economics, and the interaction between lawyers and economists, adds an interesting dimension.
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